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10,10'-Oxybisphenoxarsine (OBPA)
Pesticide Registration Standard

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Pesticide Registration Standard

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10, 10'-Oxybis-10H-phenoxarsine
(OBPA)

Pesticide Registration Standard

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I. HOW TO REGISTER UNDER A REGISTRATION STANDARD

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A. ORGANIZATION OF THE STANDARD

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. PURPOSE OF THE STANDARD

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of rereviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

C. REQUIREMENT TO REREGISTER UNDER THE STANDARD

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this standard.

D. "PRODUCT SPECIFIC" DATA AND "GENERIC" DATA

In the course of developing this standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this standard applies. Where it appeared that data from a normally applicable Guidelines requirement were actually unnecessary to evaluate these products, the standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the standard covers; if so, the standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are _product specific_, i.e. data that relates only to the the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. _Generic_ data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular _ingredient_ of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of _all_ products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this standard may similarly request approval for only certain use patterns.

E. DATA COMPENSATION UNDER FIFRA SECTION 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which are described by all the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, U.S. Department of Agriculture (USDA) or Food and Drug Administration (FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this standard, or for registration of a new product under this standard, accordingly must determine which of the data used by EPA in developing the standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which arespecific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for those data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this standard is found in the Guidance Package for this standard.

F. OBTAINING DATA TO FILL "DATA GAPS"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this standard. Such instances of missing but required data are referred to in the standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two ormore registrants may agree to share in the costs of producing data for which they are both responsible.

The standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The standard also points out that to be registrable under the standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product by product" basis. (Although the standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule. Persons who wish to obtain registrations for new products under this standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. AMENDMENTS TO THE STANDARD

Applications for registration which propose uses or formulations that are not presently covered by the standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the standard, will automatically be considered by the Agency to be requests for amendments to the standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities.

Independent of the development of any one standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the standard applies, these ingredients will be pointed out in the Guidance Package.

II. REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description of Chemical
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration Under the Standard
F. Acceptable Ranges and Limits
G. Required Labeling
H. Tolerance Reassessment
I. New and Amended Registrations Under This Standard

A. INTRODUCTION

This chapter represents the Agency's regulatory position and rationale based on an evaluation of all registered products containing 10,10'-oxybis-10H-phenoxarsine (OBPA) as the sole active ingredient. After briefly describing the chemical, this chapter presents the regulatory position and rationale, and the criteria for registering products containing this chemical. These criteria include labeling considerations. A summary of data requirements is contained in Chapter III. Discussions of the data upon which this regulatory position is based are presented in each of the disciplinary Chapters, IV through VIII.

10,10'-oxybis-10H-phenoxarsine (OBPA) was originally placed on the Rebuttable Presumption Against Reregistration (RPAR) list because it is an arsenical. Inorganic arsenicals are suspected oncogens, mutagens and teratogens. After a thorough review of the uses of this chemical the Agency concluded that because the compound did not leach from the treated material, the exposure and, hence the risk, associated with the uses of this chemical was extremely small (USEPA, 1979, MRID GS044070). The Agency's RPAR decision document concluded that 10,10'-oxybis-10H-phenoxarsine (OBPA) does not exceed any of the toxicology criteria in 40 CFR 162.11(a)(3). The chemical was subsequently returned to Registration Division.

B. DESCRIPTION OF CHEMICAL

The acronym OBPA will be used throughout this standard in lieu of other chemical or trade names. OBPA is an arsenic-containing heterocyclic compound which is incorporated into flexible vinyl sheeting and extrusions, silicone caulking compounds, thermoplastic adhesives, polyurethane, latex emulsions (not including paints, ink bases and textiles) to prevent the growth of microorganisms. Although the materials themselves are resistant to microbial attack, the plasticizers and other additives used to produce flexible vinyl (OBPA is not used in rigid vinyl), caulking and adhesive compounds are subject to microbial attack resulting in staining and degradation.

All OBPA manufactured in the United States is made by Cordova Chemical Company of Sacramento. The technical material is sold only to Ventron Corporation of Beverly, Massachusetts, which formulates it in 1.0, 2.0, 3.0, and 5.0 percent formulations. There are three other end-use registrants: Comark Plastics Division, Seymour Chemical Association, and Duracote Corporation.

C. REGULATORY POSITION

The Agency has considered the limited amount of scientific data obtained from the open literature as of August 14, 1981, the Agency's April 20, 1979, decision document to remove OBPA from the Rebuttable Presumption Against Registration (RPAR) list, and the data submitted by the registrants up through the time of publication of this standard.

Based on the review of this information, the Agency finds that:

1. OBPA, as described in this standard, may be registered for sale, distribution, reformulation, and use in the United States,
2. The use of closed systems preclude worker exposure and essentially all of this compound is retained within the treated material,
3. If label directions and precautions are followed, OBPA does not cause any unreasonable adverse effects to man or the environment. Hence, none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded,
4. OBPA products currently registered may be reregistered subject to the conditions imposed in this standard and with the subsequent submission of required data. New products may be registered under this standard and are subject to the same requirements.

D. REGULATORY RATIONALE

1. Manufacturing-Use Products

There are no manufacturing-use products containing OBPA currently registered with the Agency.

The Agency will consider the registration of manufacturing-use products containing this compound provided that those product chemistry data listed in chapter three of this standard are submitted to the Agency.

The toxicology data currently available indicate that OBPA possesses a high order of acute oral and dermal toxicity, and is very irritating to the lungs, eyes and skin. Toxicology data also indicate that technical OBPA is not mutagenic, teratogenic, fetotoxic or embryotoxic under the test systems used. No other chronic data are available on the technical chemical. Since the current data do not indicate any toxicological concerns and because exposure is very low, no further testing will be required to support future applications for registration of manufacturing-use products, provided that (1) this chemical is used only in closed systems, and (2) no new uses which will significantly increase human exposure are added to the present list of registered pesticidal uses.

The current fish and wildlife toxicity data indicate that techical OBPA possesses a high order of acute toxicity to aquatic organisms. However, no further ecological effects testing will be required of future applications for registration of manufacturing-use products containing this compound because the current uses of this compound preclude significant environmental exposure.

Since the uses preclude significant environmental exposure, the Agency has concluded that no environmental fate testing is required of end-use products containing OBPA. The Agency has concluded that hydrolysis and activated sludge studies are necessary to understand potential impact of effluents from manufacturing-use products. However, the Agency has determined that the requirement for the activated sludge studies will be reserved, pending development of suitable protocols by the Agency.

In light of the determination of acceptable risk, the Agency will consider the registration of all manufacturing-use products of this compound.

2. End-Use Products

The end-use products of OBPA are additives used primarily for preserving fabrics and plastic materials (vinyls, polyurethane, thermoplastic adhesives, and silicone caulking compounds) against attack by fungi and bacteria. Use rates of OBPA in products are higher if the product will be exposed out of doors.

The available data on the acute toxicity of the end-use products of OBPA indicate that the inerts in the product, which are added to facilitate the manufacture of the treated materials, are the cause of the wide variability in toxicity levels between products. Because the toxicity of end-use products is highly variable based on the inerts, it is not possible to readily confirm that data on any particular product are relevant to any other specific product. The Agency is able to conclude that the available data taken as a set are sufficient to provide an understanding of end-use product acute toxicity. To avoid requiring any unnecessary testing, the Agency is prepared to accept a citing of the existing data and labeling consistent with the most toxic test conducted to date in lieu of requiring registrants of new products to do the testing. Applicants choosing to conduct the tests rather than cite the existing data may do so and will be expected to submit the data, and label the product in accordance with the testing.

The 1.0% OBPA solutions in nonvolatile plasticizer carriers showed low to moderate acute oral, eye irritation and dermal irritation. The 2.0% OBPA solutions in nonvolatile plasticizer carriers showed low to moderate acute oral, acute dermal toxicity, and dermal irritation; and showed moderate to severe eye irritation. The 3.0% OBPA solution in low viscosity carriers showed low to moderate acute oral, and acute dermal toxicity. The 5.0% solid pelletized OBPA formulation showed low acute oral and dermal toxicity.

Based on existing use patterns, the Agency has determined that there is no significant environmental or fish and wildlife exposure to the end-use products of OBPA. OBPA is not registered for use on food or feed crops, therefore no tolerances are required.

The Agency has concluded that it will continue the registration for the active ingredient 10,10'-oxybis-10H-phenoxarsine (OBPA) for the following reasons:

a) The formulations of OBPA are incorporated into vinyl plastics, silicone caulking componds, thermoplastic adhesives, polyurethane and textiles which chemically and physically retain the active ingredient during the lifetime of the treated material. Because it is not released from the treated material, no acute or subacute toxicity to man, domestic animals, fish and wildlife are expected from OBPA.

b) Based on available data, OBPA has been found to cause no adverse effects as specified in 40 CFR 162.11.

c) In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as amended, (FIFRA) the Agency's policy is not to routinely cancel or withhold the registration of products merely for lack of data (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, the publication of this standard provides a mechanism for identifying data needs, and registration under this standard allows for upgrading of labels while the required data are being generated. When these data are received and reviewed, the Agency will reassess the registration of the chemical.

As the use patterns do not fall within the public health criteria established under the Agency's efficacy waiver policy, (44 FR 27932, May 11, 1979), a discussion of the OBPA efficacy data is not required in this standard.

E. CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be subject to this standard, the OBPA products must meet the following conditions:

- contain 10,10'-oxybis-10H-phenoxarsine (OBPA) as the sole active ingredient;
- bear required labeling; and
- conform to the acute toxicity limits, product composition and use pattern requirements stated in this standard.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in this standard. These include a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide

Act (FIFRA), as amended, 7 U.S.C. 136a(c)(1)(D). As discussed in Chapter I, applicants for registration under this standard must contact the Registration Division for specific instructions, including updated information contained in the guidance package on data requirements and companies whose data must be cited and to whom compensation must be offered.

F. ACCEPTABLE RANGES AND LIMITS

1. Manufacturing-Use Products

No manufacturing-use products are currently registered. However, based on the efficacy and use patterns of end-use products, a manufacturing-use product of any concentration is registrable when labeled according to toxicity categories determined by the results of appropriate product chemistry and toxicology data.

2. End-Use Products

a. Product Composition Standard

Currently the Agency has minimal information on acceptable ranges and limits for the product composition of end-use products containing OBPA. To be covered under this standard, registrants of end-use products containing OBPA must certify ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of end-use products containing OBPA, under a general-use classification, regardless of their toxicity category, provided that they bear appropriate precautionary labeling.

c. Use Pattern Limits

To be registered under this standard, end-use products containing OBPA must be labeled as a microbicidal (additive) agent.

G. REQUIRED LABELING

To be considered under this standard, end-use products must bear directions for use as a bacteriostatic and fungistatic agent to be incorporated into one or more of the following materials: vinyl plastics, silicone caulking compounds, polyurethane, thermo-plastic adhesives, and textiles.

Because of the potential for eye and skin irritation, all products containing OBPA must bear labeling which requires the use of goggles and gloves and the use of "closed systems" during the manufacturing process. Other than this labeling, there are no unique precautionary statements which must appear on the OBPA labeling.

The guidance package will provide an updated list of all precautionary statements as specified in Title 40, CFR Section 162.10 for this type product. The Agency may, after review of data submitted under this standard, impose additional label requirements.

H. TOLERANCE REASSESSMENT

These products are not used in food and feed crops and are not applied to food preparation areas. Therefore, the current uses of OBPA products are not subjected to the requirements to obtain a tolerance under the provisions of the Federal Food, Drug, and Cosmetic Act as administered by this Agency. No tolerance reassessment is necessary for this standard.

I. NEW AND AMENDED REGISTRATIONS UNDER THIS STANDARD

Principal among the goals of the Registration Standards process is the reregistration of currently registered pesticide chemicals. These goals also include the creation of a mechanism for the registration of new and added uses of a chemical. Although OBPA bears current registration for use incorporation into plastics and fabrics with a limited number of end uses, it may be anticipated that new sites of application will be sought. While it is virtually impossible to anticipate future registration actions with any degree of certainty, it is possible to define the general applicability of this standard to future uses of this chemical.

The Agency, in its review of the current data base, has determined that OBPA does not appear to present any unreasonable adverse effects as it is currently used. The Agency will adopt the results of the standard for all future registration actions. Additional data will not be required except under those circumstances in which major alterations in use pattern and formulation might be sought. Expanding OBPA's use, for example, into non-food uses where exposure to man and the environment is essentially similar to the present uses would be deemed covered by this standard. An example of where an alteration to the standard would be necessary would be the use of OBPA in plastics which will be in direct, prolonged contact with skin. Should such a registration be sought, the Agency may seek additional data evaluating any chronic effects as a result of such exposure. Similarly, the addition or substitution of inert ingredients into either a manufacturing-use or end-use product, the alteration of a manufacturing process, or the change of a use pattern might necessitate the submission of additional data.

III. SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. INTRODUCTION

Applicants for registration of end-use OBPA products must cite or submit the following information on the physical/chemical properties, composition, fate and toxicity of the proposed product. Data in this standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in the determination of substantially similar products. (See Chapter I for discussion of substantially similar products). The sections of the Proposed Guidelines which describe the types of data and when they are required [43 FR, No. 1332, 29696 of July 10, 1978; and 43 FR, No. 163, 37336of August 22, 1978] are listed before each requirement.

A justification for these requirements is provided in the Guidelines. Applicants for the reregistration of end-use OBPA must submit all information identified as data gaps (see charts). A discussion of why data additional to those already submitted are necessary, or why data normally required are not necessary for this chemical, are explained in footnotes to the charts. The footnotes are at the end of all charts. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing, are indicated.

DATA REQUIREMENTS CHART A

10,10'-Oxybis-10H-phenoxarsine

Generic Data Requirements: ENVIRONMENTAL FATE

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.161-1	Hydrolysis	Radiolabeled Analytical Grade or Tech. Grade of A.I.	no	-	yes/ 9 months
-	Activated Sludge Metabolism	Tech. Grade of A.I.	no	-	Reserved 1/
-	Extraction Studies	Each Product	yes	GS044034,GS044062 GS044011,GS044056 GS044023,GS044080 GS044048,GS044030 GS044031,GS044041 GS044055,GS044012 GS044024	no

These data requirements are current as of October, 1981. Refer to the guidance package for updated requirements.

1. The activated sludge data will be required, pending development of an acceptable test protocol.

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DATA REQUIREMENTS CHART A

10,10'-Oxybis-10H-phenoxarsine

Generic Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Tech. Grade of A.I.	yes	00024941,GS044002 00024935,00013591 05015857,00013643	no
163.81-2	Acute Dermal Toxicity	Tech. Grade of A.I.	yes	00024935,00013643 GS044002,GS044020 GS044039,GS044004	no
163.81-3	Acute Inhalation Toxicity	Tech. Grade of A.I.	yes	00024935,GS044035 05015857,00013591	no
163.81-4	Primary Eye Irritation	Tech. Grade of A.I.	yes	00024938,00024935 GS044002,00013591 05015857,00013643	no
163.81-5	Primary Skin Irritation	Tech. Grade of A.I.	yes	00024937,00024935 00013591,05015857 00013643,GS044002	no
163.82-1	Subchronic Oral Toxicity	Tech. Grade of A.I.	yes	00024936,00024940 GS044042	no
163.82-4	Subchronic Inhalation Toxicity	Tech. Grade of A.I.	yes	00013591,05015857	no
163.83-3	Teratogenicity	Tech. Grade of A.I.	yes	GS044007	no
163.84-2 through -4	Mutagenicity	Tech. Grade of A.I.	yes	00013644,00013647 GS044007	no
163.85-1	Metabolism (Identification of Metabolites)	Radiolabeled, Analytically Pure Grade of A.I.	yes	00026092,00024935 00013591,05015857	no

These data requirements are current as of October, 1981. Refer to the guidance package for updated requirements.

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DATA REQUIREMENTS CHART B

10,10'-Oxybis-10H-phenoxarsine

Product-Specific Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identitiy & Disclosure of Ingredients	Each Product	no	-	yes/ 1/
163.61-4	Description of Manufacturing Process	Each Product	no	-	yes/ 1/
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	no	-	yes/ 1/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	yes/ 1/
163.61-7	Product Analytical Methods & Data	Each Product	no	-	yes/ 1/
163.64-3	Physical & Chemical Properties	Tech. Grade of A.I. or Each Product	no	-	yes/ 1/

These data requirements are current as of October, 1981. Refer to the guidance package for updated requirements.

1. These requirements must be fulfilled by each applicant. Data from other appplicants may not be cited. Therefore, even if the requirement has been fulfilled for some products, no references aregiven. These requirements must be fulfilled at the time of registration or reregistration.

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DATA REQUIREMENTS CHART C

10,10'-Oxybis-10H-phenoxarsine

End-Use Product-Specific Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identitiy & Disclosure of Ingredients	Each Product	yes	-	yes/ 1/
163.61-4	Description of Manufacturing Process	Each Product	yes	-	yes/ 1/
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	no	-	yes/ 1/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	yes/ 1/
163.61-7	Product Analytical Methods & Data	Each Product	no	-	yes/ 1/
163.64-3	Physical & Chemical Properties	Tech. Grade of A.I. or Each Product	yes	-	yes/ 1/

These data requirements are current as of October, 1981. Refer to the guidance package for updated requirements.

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1. These requirements must be fulfilled by each applicant. Data from other appplicants may not be cited. Therefore, even if the requirement has been fulfilled for some products, no references aregiven. These requirements must be fulfilled at the time of registration or reregistration.

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DATA REQUIREMENTS CHART C

10,10'-Oxybis-10H-phenoxarsine

Product-Specific End-Use Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Each Product	yes	00024953,GS044078 GS044077,GS044057 00013631,00013610 GS044025,00023384 GS044076,00013629 00013630,00013651 00013660,00013661 00013662,00013663 GS044060,GS044075 00023386	no
163.81-2	Acute Dermal Toxicity	Each Product	yes	GS044078,00024953 GS044075,GS044057 00013631,00023384 GS044077,00013629 00013636,00013630 00013652,00013660 00013661,00013662 00013663,00013610	no
163.81-3	Acute Inhalation Toxicity	Each Product	yes	GS044075	no
163.81-4	Primary Eye Irritation	Each Product	yes	00024956,GS044025 GS044078,00013630 GS044075,GS044057 00013632,00013636 00013653,GS044077 GS044076	no
163.81-5	Primary Skin Irritation	Each Product	yes	GS044078,00024953 GS044077,GS044079 GS044033,00013632 00013636,00013652 00013653,00013660 00013661,00013663 00013662,GS044051 GS044075,00013603 00013601,GS044076 GS044025	no
163.81-6	Dermal Sensitization	Tech. Grade of A.I.	yes	GS044020,00023377 00013630,000024946	no
163.82-2	21-Day Subchronic Dermal Toxicity	Each Product	yes	GS044017,00023377	no

These data requirements are current as of October, 1981. Refer to the guidance package for updated requirements.

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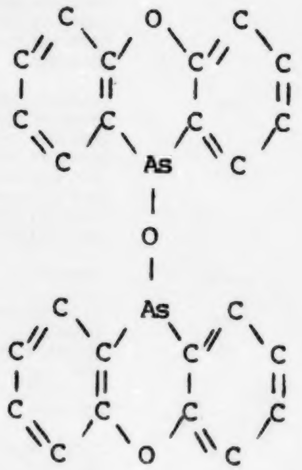
IV. PRODUCT CHEMISTRY

A. Chemical Identity
B. Manufacturing Process
C. Physical and Chemical Properties
D. Summary of Data Gaps

A. CHEMICAL IDENTITY

OBPA is a common acronym for 10,10'-Oxybis-10H-phenoxarsine, an arsenic-containing heterocyclic compound. The Chemical Abstracts Registry (CAS) number for OBPA is 58-36-6, and the EPA Shaughnessy number is 012601.

The structural formula for OBPA is:



B. MANUFACTURING PROCESS

One possible synthetic route for technical OBPA is based on U.S. Patent Number 3,701,794 (Wade, 1972, MRID 05016437) and can be summarized as follows: a reaction between arsenic trichloride and diphenyl ether at (200°C) which yields 10-chlorophenoxarsine; the latter when heated in analkaline medium gives OBPA. The actual synthetic proceedure is considered confidential business information.

C. PHYSICAL AND CHEMICAL PROPERTIES

The following data are available on the physical and chemical properties of technical OBPA. Data which are not available but required to be submitted are listed in the tables in Chapter III. Available data on technical OBPA are as follows:

1. Color

White (Ventron Corp., 1976, MRID 00013625)

2. Odor

Odorless (Dow Chemical Co., 1965, MRID 00026094)

3. Melting Point

182°C (Dow Chemical Co., 1965, MRID 00026094)

4. Solubility

OBPA is soluble in water at 10 ppm. In nonyl phenyl it is soluble, while in organic solvents it is essentially insoluble (Yeager, 1976, MRID GS044066).

5. Stability

An assay has shown that OBPA is stable. There was 99.8 percent present in 1.25-3.5 years (Ventron Corp., 1975, MRID 00013622).

6. Physical State

OBPA is a crystaline solid (Yeager, 1976, MRID GS044066).

7. Specific Gravity

1.40-1.42 (Yeager, 1976, MRID GS044066).

8. Vapor Pressure

0.05 mm at 20°C (Wade, 1972, MRID 05016437).

9. pH

5.55 (Ventron, 1981, MRID GS044069).

D. SUMMARY OF DATA GAPS

As applications for new product registrations are submitted, they must provide information as outlined in the Confidential Statement of Formula, EPA Form 8570-4.

V. ENVIRONMENTAL FATE

A. Use Summary
B. Environmental Fate Profile
C. Exposure Profile - End-Use Products
D. Summary of Environmental Fate Data Gaps

A. USE SUMMARY

The active ingredient, OBPA, is not currently marketed as a manufacturing-use product but as formulated products. It is an antimicrobial agent which is marketed generally in the form of 1-3% OBPA solutions in nonvolatile plasticizer carriers. Among the plasticizers most commonly used are epoxidized soybean oil, epoxy compounds and phthalate esters. The OBPA solutions are used to protect plastic compounds against microbial and fungal attack. OPBA is also formulated as 1-3% aqueous solutions with various polymers to form solid resin concentrates. In this form, OBPA is immobile in the plastic matrix and it remains physiologically stable.

OBPA is formulated at 5.0%, which is sold as a homogeneous solid in pelletized form. It is used in polyvinyl resins, polyurethane and related polymeric compositions.

The OBPA formulations are registered for the control of microorganisms on the following items: flexible vinyl sheeting and extrusions, silicone caulking compounds, thermoplastic adhesives, polyurethane, latex emulsions (not includig paints), ink bases and textiles.

Although flexible vinyls and silicones in themselves are resistant to microbiological deterioration, the use of OBPA formulations in products made from these materials is necessary due to microbial susceptibility of plasticizers, lubricants, and fillers which are added to obtain desirable physical and chemical properties. In addition, OBPA protects products from fungi which grow on superficial dust, dirt, or grease on their surfaces.

B. ENVIRONMENTAL FATE PROFILE

The uses of this compound precludes any significant environmental exposure from end-use products because it is incorporated and bound within plastics and fabrics. While there is some leaching from newly made plastic during an initial weathering period, the levels of OBPA found in solvent extracts indicate that a 50 ppb maximum daily dietary intake of arsenic in drinking water, recommended by USHEW (1962, MRID GS044055), will not be exceeded. After the initial period of weathering, end-use products containing OBPA leached, on the average, far less than the recommended 50 ppb maximum dietary intake (Hamilton, 1978, MRID GS044024; and Ventron Corp., 1978, MRID GS044056).

C. EXPOSURE PROFILE

1. Direct Exposure

The potential for direct human exposure is limited primarily during the manufacture of products containing OBPA. Formulated products contain only 1.0, 2.0, 3.0 or 5.0% OBPA. Materials incorporating OBPA are produced in "closed systems" because of the extreme irritating nature of the compound. Two separate surveys of Ventron Corporation reformulation sites for airborne concentrations of organic arsenic showed exposure readings were 0.18 and 0.002 mg of inorganic arsenic per cubic meter of air (Kugler, 1974, MRID GS044034 and Weingast, 1976, MRID GS044062). These data, while limited, indicate a very low exposure to airborne OBPA in the work environment.

After reviewing these data, the Agency has determined that the use of a "closed system" manufacturing process significantly limits the potential for direct OBPA exposure to humans.

2. Indirect Exposure

Indirect routes of exposure to OBPA are limited to finished products containing the compound. Very small amounts of OBPA are used in finished products. Indoor and outdoor plastics contain 0.03%(w/w) and 0.05% (w/w) of OBPA, respectively. Caulking compounds contain 0.03% to 0.05% (w/w) OBPA. Thermoplastic-based adhesives contain 0.03% (w/w) OBPA. Treated textiles (drapes and matress ticking) contain 0.04% to 0.10% OBPA. These limited indirect exposure routes consist of: dermal, inhalation and dietary exposure.

a. Dermal Exposure

Dermal exposure comes from vinyl products used in a recreational setting (e.g. lawn chairs, pool liners, and treated vinyl used in boat seats). In summer, exposure is compounded by generally high temperatures, the presence of water or perspiration, and wearing of swimming attire allowing for maximal skin contact.

Numerous researchers have performed extraction studies of plastics containing OBPA. Using 10% (v/v) acetic acid, 0.1% (w/v) sodium carbonate or distilled water for two 24 hour extraction procedures, Cadmus (1973, MRID GS044011 & GS0044012) extracted less than 20 percent and less than 10 percent of the OBPA found in heavy and light gauge plastics, respectively.

Ventron (1978, MRID GS044056) extracted OBPA with 10% (v/v) acetic acid, 0.1% (w/v) sodium carbonate, distilled water or simulated basic sebum for 48 hours from swimming pool liners prepared in the laboratory. The results of this study indicate that approximately 10 to 15 percent of the OBPA was extracted from the pool liner.

In a second study by Ventron (1978, MRID GS044056), commercially prepared heavy vinyls were extracted for 48 hours using distilled water, simulated acid sebum, simulated basic sebum, 0.1% (w/v) sodium carbonate, 10% (v/v) acetic acid or stabilized chlorinated pool water. The results of this study indicate that the amount of OBPA lost from commercially prepared vinyl films does not differ dramatically from the laboratory prepared samples.

Hamilton (1978, MRID GS044023) extracted vinyl films containing 0.026% and 0.04% OBPA at 37°C in distilled water from 5 to 45 days. This study indicates that approximately 62 and 63 percent leached from plastic initially containing 0.026% and 0.04% OBPA. No OBPA leached after 25 and 35 days from plastic containing 0.026% and 0.04% OBPA, respectively.

These studies indicate that small amounts of OBPA can be leached from plastic used in plastics found in recreational and outdoor settings. These studies also indicate that the amount of leaching of this compound is limited primarily to situations of high heat and humidity.

b. Inhalational Exposure

A second route of exposure is through vaporization of OBPA from vinyl-containing wall coverings, shower curtains, and other treated products.

The vapor pressure of OBPA is less than 1×10^{-6} mm Hg, the limit of detectablity of the method (Skinner and Sherman, 1978, MRID GS044068). Inhalational exposure to OBPA is, therefore, expected to be negligible because the vapor pressure is negligible.

c. Dietary Exposure

A third exosure possibility is OBPA via water. If caulking compounds are used, some OBPA will be leached into appliances which contact food surfaces.

The Consumer Product Safety Commission (CPSC) (Porter, 1973, MRID GS044048) conducted an extractability study of a silcone caulking compound in an automatic dishwasher for two hours at 80°C. Two ml of corn oil and 0.2% (w/v)of dishwashing detergent were added to the water to simulate use conditions. The results of this study indicate that the 39 percent of the arsenic extracted from the sealant contributed 28 ppb of arsenic to the wash water.

The CPSC (Kirkpatrick, 1977, MRID GS044030 and Kirkpatrick, 1977, MRID GS044031)performed additional extractability studies on two additional silicone sealants which contained OBPA, one of which was not recommended for use in dishwashers. The results of this study indicate that neither sealant would contribute more than 50 ppb to the wash water.

Major Appliances Laboratories (1975, MRID GS044041) conducted two extractability studies of a silcone sealant in two dishwashers. 50 grams of citric acid were added to the wash water to simulate aging conditions of the appliance. After 28 cycles the arsenic content of the water never exceeded 25 ppb. Analysis of the sealant material indicated that over 70 percent of the arsenic remained in the sealant after 30 cycles.

The above studies indicate that less than 50 ppb arsenic is leached from the caulking compounds used in dishwashing appliances. By contrast, up to 50 ppb arsenic is permitted in public drinking water by the USHEW (1962, MRID GS044055).

The conclusions of a detailed exposure analysis performed by this Agency (EPA, 1979, MRID GS044070), using the data from the above studies, are summarized in Table 1.

TABLE 1

SUMMARY OF EXPOSURE TO OBPA 1/

Treated Products/Uses	Primary Route of Exposure	Amount of OBPA Exposure (ug/kg/hr) 70 kg person	50 kg person
Vinyl Wall Coverings	Inhalational 4/	0.00 2/	0.00 2/
Seats & Chairs	Dermal 5/	7.14	10.00
Swimming Pool Liners	Dermal 3/	0.91	1.27
	Oral 3/	0.91	1.27
Food Contact Surface Caulking Material	Dietary 6/	0.01	0.02
Shower Curtain & Mattress Cover	Inhalational 7/	0.00 2/	0.00 2/

1/The references used in the original exposure analysis include: Cadmus, 1973, MRID GS044012; Kugler, 1974, MRID GS044034; Weingast, 1976, MRID GS0440062; Ventron Corp., 1978, MRID GS044056; Skinner and Sherman, 1978, MRID GS0440068; Hamilton, 1978, MRID GS044023; and Hamilton, 1978, MRID GS044024.

2/The estimated exposure to OBPA from inhalation was calculated to be 0.0004 ug/kg/hr for a 70 kg person and 0.00056 ug/kg/hr for a 50 kg person. This exposure is low enough that it is reported as 0.00.

3/An oral estimate was not included in the exposure analysis performed by the Agency in 1979 (USEPA, 1979, MRID GS044070). The calculation of oral exposure has been estimated to be essentially the same as the dermal exposure:

$$\text{Oral Exposure} = \frac{\text{OBPA conc. in pool water x quantity of water swallowed}}{\text{Weight of Person}}$$

$$\text{Oral Exposure} = \frac{0.02 \text{ mg/l x } 0.5 \text{ l}}{70 \text{(or 50)kg}}$$

4/Inhalational Exposure = (area of 4 walls in a room) x (mg OBPA/M^2 of wall covering) x (10% OBPA vaporized per yr) x (1M^3/hr breathing rate/7 hr day) ÷ (weight of person)

5/Dermal Exposure (seats/chairs) = (area of exposed skin) x (mg OBPA/M^2 vinyl leached/hr) x (0.5 l perspiration) ÷ (weight of person)

6/Dietary Exposure = (conc. OBPA in water) x (vol. of water which dries on plate) ÷ (weight of person)

7/Inhalational Exposure = (area of vinyl surface) x (mg OBPA in vinyl) x (volume of small room) x (1% OBPA vaporized/ yr) x (1M^3/hr breathing rate) ÷ (weight of person)

After a thorough review of the manufacture and use of end-use pesticides and products the Agency has concluded that the use "closed systems" and an extremely small amount of the material released from plastics treated with this material will not result in significant human exposure to this compound.

D. SUMMARY OF DATA GAPS

To understand the potential environmental impact from the manufacturing of OBPA, hydrolysis, and activated sludge metabolism studies are required. However, the activated sludge study is being delayed until the Agency completes development of the protocol.

VI. TOXICOLOGY

A. Toxicology Profile
B. Human and Domestic Animal Hazard Assessment
C. Summary of Data Gaps

A. TOXICOLOGY PROFILE

1. Manufacturing-Use OBPA

a. Acute Oral Toxicity

Olsen (1959, MRID 00024941) administered 2.0, 3.98, 7.95 and 15.8 mg/kg to female rats of an unspecified strain. Four animals per dose were administered OBPA (unspecified percent A.I.) as a 0.0795 percent corn oil suspension. Body weights and few gross necropsy data are available. No histopathology data are available. The study indicates that extensive kidney and liver damage were observed at autopsy. Only two animals died in the study: at the 3.98 and 15.8 mg/kg doses. No LD_{50} calculation was performed by the author and hence the toxicity category of this product is not known.

In a second study performed by Olsen (1959, MRID 00024941), 15, 31, 63, 125 and 252 mg/kg was administered to female rats of an unspecified strain. Two animals per dose were administered OBPA (unspecified percent A.I.) as a 1.25 percent corn oil suspension. Body weight data are available. Some data are available indicating that the liver and kidney showed extensive damage from treatment. This study also indicates that there may have been some histopathological examination of tissues was made in this test. All but one animal at the 15 mg/kg dose died during the study. While no LD_{50} calculation was performed by the author, the LD_{50} for the test compound could be below 15 mg/kg and could place this product into toxicity category I.

Female rats (unspecified strain) were administered a 0.0795% corn oil solution and a 1.25% corn oil suspension of OBPA by Dow (1964, MRID 00024935) by intubation. Four animals received the 0.0795% solution and two animals per dose received the 1.25% suspension. The estimated LD_{50} is 15 mg/kg, placing this material into toxicity category I.

Male Porton-Wistar rats and male Duncan-Hartley guinea pigs were administered, by gavage, technical (unspecified percent A.I.) OBPA by International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857). All doses of the test compound were administered in 0.5% (w/v) Triton-X plus 0.5% (w/v)carboxymethylcellulose. Ten rats per dose were administered 25.0, 29.8, 35.4, 42.0, 50.0, 70.0 and 100.0 mg/kg of the test compound. Ten guinea pigs per dose were administered 17.7, 21.0, 25.0, 29.8 mg/kg and six guinea pigs per dose were administered 35.4, 50.0, 70.8 and 100.0 mg/kg of the test compound. Survivors showed signs of abdominal tenderness, tenseness, dyspnea, ataxia and sluggishness. Decedents showed hepatic, lung and kidney involvement. Hepatic involvement reduced in severity by day 21. Survivors appeared to be normal, except for a slight increase in portal tract mononuclear cells. The LD_{50}'s of the test material for rats and guinea pigs are: 40 mg/kg and 23.8 mg/kg, respectively, placing the test material into toxicity category I.

Anspach (1977, MRID 00013643) estimated the oral LD_{50} of technical (99.9%)OBPA by dosing five male and five female albino rats (unspecified strain) per dose level. Animals were administered the test compound as a 0.215% or a 2.0% corn oil suspension. Doses of technical OBPA in the 0.215% suspension were: 2.15, 4.64, 10.0, 21.5 and 46.4 mg/kg. Doses of technical OBPA in the 2.0%suspension were: 21.5, 46.4 and 100 mg/kg. The calculated LD_{50} of the 0.215%suspension in male and female animals is: 20.0 and 27.1 mg/kg, respectively. The calculated LD_{50} of the 2.0% suspension in male and female animals is: 68.1 and 43.0 mg/kg, respectively. Extensive gross necropsy of all animals briefly showed the following: congested lungs, kidneys and adrenals, gastro-intestinal tract filled with whitish material and fluid, depleted fat reserves. Toxic signs include: depression, emaciation, diarrhea and labored respiration. The results of this test place technical OBPA into toxicity category I.

Anspach (1977, MRID GS044002) tested the acute toxicity of OBPA by dosing five male and female Sprague-Dawley rats with the technical material (95.6% A.I.). The material was administered as a 0.5% (w/v) suspension in corn oil at the following dose levels: 4.64, 10.0, 21.5, 46.4 and 100.0 mg/kg. Gross necropsies were performed on all animals. Toxic signs included diarrhea, emaciation and bloody stains around the muscle. Rats exhibited congested adrenal, kidneys and lungs, irritated gastro-intestinal tracts, and some animals showed darkened livers and depleted fat stores. The LD_{50} for male and female rats is: 36.9 and 31.6 mg/kg, respectively, placing this material into toxicity category I.

After reviewing the above studies for technical OBPA, the Agency has determined that this material possesses a high order of acute oral toxicity and falls within toxicity category I.

b. Acute Dermal Toxicity

Dow (1964, MRID 00024935) administered OBPA (unspecified percent A.I.) as a 20 percent suspension in dipropylene glycol methyl ether to the skin rabbits (unspecified sex and strain) under occlusive wrap. After an exposure of 24 hours the test animals exhibited severe skin burns. Two animals were used for each of the following doses: 100, 200 and 500 mg/kg. The dermal LD_{50} was estimated as between 100 and 200 mg/kg, placing this chemical into toxicity category I.

Anspach (1977, MRID 00013643) dosed four rabbits (unspecified strain) per dose with 100, 215, 464, 1000 and 2150 mg/kg for 24 hours. Both abraded and intact skin was used in this study. The test compound (99.9% technical OBPA) produced moderate erthyema and edema with diffuse blanching, desquamation and coriaceousness of the exposed skin. Only two animals died from treatment: one at 100 and one at 2150 mg/kg. The LD_{50} is estimated as exceeding 2150 mg/kg. Extensive gross necropsy revealed effects primarily limited to the irritative nature of the compound. The results of the test place technical OBPA into toxicity category III.

Anspach (1977, MRID GS044002 and Egger and Ison, 1976, MRID GS044020) dosed four male and female albino rabbits (unspecified strain) with 215, 464, 1000 and 2150 mg/kg of technical OBPA (95.6% A.I.). The undiluted material was applied to both abraded and intact skin for 24 hours under occlusive wrap. Toxic signs include diarrhea, emaciation, necrosis, edema and blanching of the test site, labored respiration and bloody discharge from the nose and ears. Gross necropsy of decedants revealed congested lungs and kidneys, irritated GI tract and peritoneal walls, depleted fat stores, spotted livers, heammorrhagic heart. Gross necropsy of survivors was unremarkable. The LD_{50} is 414 mg/kg, placing this material into toxicity category II.

Litton Bionetics (1978, MRID GS044039) administered technical OBPA (96.8% A.I.)to four male Charles River rats per dose. The test material was suspended in corn oil and administered at the following doses: 21.5, 46.4, 100.0, 215.0, 464.0, 1000.0 and 2150.0 mg/kg. Toxic signs include nasal and eye discharge, reduced coordination, activity and tremors. Necropsy revealed pulmonary, adrenal, liver and GI tract involvement. The LD_{50} is 121 mg/kg, placing this material into toxicity category I.

Babish (1978, MRID GS044004) performed a range-finding and final LD_{50} determination on OBPA (unspecified percent A.I.). In the range-finding study, one male and female Spraque Dawley rat per dose were administered 280, 500, 900, 1600, 2800 and 5000 mg/kg of the test material under occlusive wrap for 24 hours. The dermis of all animals remained intact. One animal died at each of the three lower doses and all animals died at the other higher doses. Gross necropsy of the decedents was unremarkable. In the main study, five males and females were administered 100, 200, 400 and 800 mg/kg of the test material in corn oil under occlusive wrap for 24 hours. The dermis of all animals remained intact. The LD_{50} is 330 mg/kg, placing this material into toxicity category II. Necropsy of all decedents was unremarkable. Toxic signs for both tests included: reduced activity, ataxia, urinary incontinence, bloody nasal discharge and chromodacryorrhea.

After reviewing the above studies for technical OBPA, the Agency has determined that this material possesses a high order of acute dermal toxicity and falls within toxicity category I.

c. Acute Inhalation Toxicity

Dow (1964, MRID 00024935) studied the inhalation toxicity of technical OBPA (unspecified percent A.I.) by exposing white rats (unspecified sex and strain) to a saturated atmosphere for seven hours. Two trials were performed with the test material at either room temperature or at 100°C. Four animals per trial, ptus one control afimal, were placed in a 19 liter chamber and exposed to an atmosphere which changed at a rate of one liter per minute. All test animals in both trials showed mild upper respiratory changes (unspecified) fromexposure to the test material either during the test or up to two weeks following exposure. No analysis of air samples was performed to confirm that the animals actually were exposed to the test compound.

Leong (1969, MRID GS044035) exposed eight rats (unspecified sex and strain) to OBPA (unspecified percent A.I.) to determine the effects of aerosol exposure to the tissue of the eyes and respiratory tract. A 2% (w/v) solution of OBPA in polyethylene glycol-200 was dispersed as an aerosol at a concnetration of 36.6 lamda per liter. Animals were individually housed in plethyographs with their heads protruding into a tubular exposure chamber. Respiratory rates of the animals were measured prior to, during and after the 15 minute exposure. All animals exhibited eye and nasal irritation and reduction of respiratory rates and dypsnea. Respiratory rates decreased 50 to 60 percent of the control value for several hours after exposure and subsequently returned to normal with no latent effects. Two animals examined immediately after exposure exhibited slight nasal discharge. Histopathological examination of these animals revealed a scant amount of mucus and a few polymorphonuclear leukocytes in the laryngeal lumen. Gross examination of two animals three days after exposure were unremarkable while histopathological examination of one of these two animals revealed polymorphonuclear leukocytes in and on the tracheal epithelium. The histopathology of these animals is compatible with upper respiratory irritation. No ocular effects were seen in this study.

International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857) estimated the LC_{50} of technical OBPA (unspecified percent A.I.) by exposing five male Duncan-Hartley guinea pigs per trial for varying time periods and dosages. The inhalational exposure dosage was calculated as the product of the dosage multiplied by the length of exposure. The mean particle size of the test compound was estimated as between 4 to 5 microns. Air samples were analyzed to assure that the animals were exposed to the test material. Toxic signs included rales, bloody nasal discharge and mild shock. Examination of the lungs, the only organs necropsied, showed intense pulmonary congestion, hemorrhaging and edema. The LC_{50} for the test compound is estimated to be 1,279 mg/L, placing this compound into toxicity category IV.

After reviewing the above studies for technical OBPA, the Agency has determined that this material possesses a low order of acute inhalation toxicity. While this material is a mild to moderate pulmonary irritant, the results of these acute toxicity studies place technical OBPA into toxicity category IV.

d. Primary Eye Irritation

Olsen (1959, MRID 00024938 and Dow, 1964, MRID 00024935) instilled OBPA (unspecified percent A.I.), both undiluted and as a 10% w/v suspension in propylene glycol, into the eyes of two female rabbits (unspecified strain). One eye was washed and the second eye remained unwashed. The washed eye received a two minute wash within 30 seconds after instillation of the test material. Instillation of the undiluted material resulted in slight pain and conjunctival involvement. Washing of the eye reduced these effects. No effects were seen on the seventh day. Instillation of the 10% solution resulted in slight pain and moderate corneal and conjunctival involvement. Washing reduced, but did not eliminate, ocular involvement. Effects of the 10% solution, including corneal involvement, persisted through day 7. The results of this study place the undiluted material and 10% solution of the test material into toxicity categories IV and I, respectively.

Technical (unspecified percent A.I.) OBPA was administered in the eyes of female New Zealand white rabbits by the International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857). The 0.1 ml of the test compound was administered with 5% DMSO in PEG 300 solvent. The following mixtures were administered without washing after instillation into the eyes: PEG 300 solvent control; a solution containing 0.1%, 0.25% or 0.5% w/v of the test compound with DMSO/PEG 300 solvent; 0.5% w/v of was administered with 5% DMSO in PEG 300 solvent. The following mixtures were administered without washing after instillation into the eyes: PEG 300 solvent control; a solution containing 0.1%, 0.25% or 0.5% w/v of the test compound with DMSO/PEG 300 solvent; 0.5% w/v of the test compound in PEG 300. To determine the effect of eye washing, another set of rabbits received a 37°C saline eye wash after instillation of 0.1% w/v of the test compound in DMSO/PEG 300. Intraocular pressure was measured before and at 10 and 60 minutes after instillation of the test material.

Instillation of the solvent into the eye of test animals produced very mild conjunctivitus. The 0.5% w/v solution produced corneal opacity and moderate to severe conjunctivitus with the iris remaining normal at 14 days. The 0.25%w/v produced similar but less severe effects. The 0.1% w/v solution produced transient and mild effects corneal and conjunctivae involvement. Solutions containing 0.5% w/v with PEG 300 produced effects similar to the 0.5% w/vsolution containing both DMSO and PEG 300. Eye washing after instillation of the test material indicates that the washing process aggravates the eye, resulting in increased ocular injury. The results of this study place this material into toxicity category I.

An eye irritation study was performed by Anspach (1977, MRID 00013643). Instillation of the technical OBPA (99.9%) into the eyes of six albino rabbits (unspecified sex and strain) produced corneal opacity, conjunctivitis and iritis which persisted through 72 hours, the duration of the test. The average Draize score was 71 out of a possible 110, placing this chemical into toxicity category I.

Anspach (1977, MRID GS044002) instilled technical OBPA (95.6%) into the eyes of six rabbits (unspecified sex and strain). The test compound produced conjunctivitis in all animals and severe corneal opacity in half of the animals. The primary eye irritation score is 62 out of 110, placing this material into toxicity category I.

After reviewing the above studies for technical OBPA, the Agency has determined that the irritating nature of this material to the eye places this material into toxicity category I.

e. Primary Skin Irritation

Olsen (1959, MRID 00024937 and Dow, 1964, MRID 00024935) tested the dermal irritation of OBPA (unspecified percent A.I.). The test material was applied to the ear of one rabbit and abdomen of two rabbits (unspecified sex and strain). The dermis of the abdomen was both abraded and intact. The test material was administered as a 10% w/v solution in dipropylene glycol methyl ether. Application of the test material to both intact and abraded skin of the abdomen and the ear results in hyperemia, edema, necrosis, exfoliation and formation of a scab and scar tissue through day 21 of observation. Results of this test place this material into toxicity category I.

A primary skin irritation study was performed by International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857). Technical (unspecified percent A.I.) OBPA was diluted 1:3 in water containing 0.5%carboxymethylcellulose and 0.5% Triton X-100. The diluted test material was administered as a 0.2 ml dose under occlusive wrap to six male Duncan-Hartley guinea pigs for six hours per day for five days. A similar number of animals were dosed only with the solvent. Treatment produced erythema progressing to escherosis with healing commensing five days after the last application. The results of this test place this material into toxicity category II.

Anspach (1977, MRID 00013643) tested technical OBPA (99.9% A.I.) by placing 0.5 gm of the test substance, under occlusive wrap, on the skin of six albino rabbits (unspecified sex and strain). Patches of both intact and abraded skin were used in this test. The test compound produced blanching of the skin with slight to severe edema and peripheral and spotted erthyema. The primary irritation index of this product is 5.79 out of a total possible score of 8.0, placing technical OBPA into toxicity category II.

Anspach (1977, MRID GS044002) applied OBPA (95.6% A.I.), under occlusive wrap, to both intact and abraded skin of six albino rabbits for 24 hours. The test material produced slight erythema and edema and blanching. The primary irritation index was 3.17 out of eight, placing this compound into toxicity category III.

After reviewing the above studies for technical OBPA, the Agency has determined that the irritating nature of this material to the skin places this material into toxicity category I.

f. Subchronic Oral

Frantz and Shrader (1959, MRID 00024936 and Oxen, 1959, MRID 00024940) administered 0, 1, 10, 30, 100 and 300 ppm of OBPA in the diet. The percent active ingredient was not specified in the report. Ten rats/sex/dose were used in this study. Food consumption was measured over 30 days of the 35 day study. Animals were weighed twice weekly to day 28 and once per week to day 35. Terminal hematology of five female rats at each of the following doses: 0, 100 and 300 ppm. Lungs, heart, liver, kidneys, spleen, and testes of all moribund animals and may have been performed on all decedents and sacrificed animals were removed and weighed. Portions of the pancreas and adrenals were also examined. Growth of all animals in the 100 and 300 ppm level was retarded, possibly due to reduced food consumption. The final average liver weight was significantly increased and there was a significant increase in the weight of the testes. Histopathological examination reveals proliferation of the portal portion of the bile duct, an effect which may be expected from arsenic. Analysis of the liver and kidneys for arsenic content reveals a significant dose/response accumulation of arsenic in these organs, an effect which may be expected from arsenic. The NOEL in this study is 10 ppm.

McCollister et al. (1969, MRID GS044042) administered OBPA (unspecified percent A.I.) to ten Sherman rats/sex/dose for 92 days at the following doses: 0, 0.03, 0.1, 0.3, 1.0 and 3.0 mg/kg/day. Hematology was performed at 28, 42 and 84 days into the study. Urinalyses were performed at 7, 32 and 88 days into the study. SPGT was determined on days 7 and 58. Hair was analyzed for arsenic at day 88. The following organs were examined and weighed: heart, liver, kidney, spleen, testes and brain. Portions of the following organs were examined microscopically: lung, trachea, urinary bladder, aorta, stomach, colon, small intestine, esophagus, thyroid, pancreas, skeletal muscle, peripheral nerve, prostrate, adrenals, seminal vesicle, ovary uterus and thymus. The liver, kidney and fat were analyzed for arsenic content.

No remarkable toxic signs were observed and there was 100 percent survivalship in this study. Growth retardation was evident only in the high dose group, possibly associated with reduced food consumption. Results of hematological, urinalysis and clinical chemistry proved unremarkable. Gross necropsy revealed a significant reduction or absence of fat from the mesentary of high dose animals. No other abnormalities were noted in necropsy. The only significant microscopic finding were lesions in the livers of high dose animals and inflammatory cellular infiltrates in the periportal area with bile duct hyperplasia. Arsenic tended to bioaccumulate in the liver and kidney at all doses, in the fat at the 0.3, 1.0 and 3.0 mg/kg/day doses and in the hair at the 1.0 and 3.0 mg/kg/day doses. The NOEL in this study is 1.0 mg/kg/day.

The results of these studies indicate that the liver, kidney and bile duct are affected by the test material. Bioaccumulation of arsenic occurs in the liver, kidney and hair at all dose levels, an effect which might be expected from the consumption of arsenic.

g. Subchronic Inhalation

25 male Porton-Wistar rats and 25 male Duncan Hartley guinea pigs were exposed by International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857) to 1 to 2 mg/M^3 of technical (unspecified percent A.I.) OBPA for five days per week for 30 days. Air samples were made at 30 minute intervals to assure that animals were being exposed to the test material. Half of the control and test animals were sacrificed 48 hours after exposure. The remaining animals were sacrificed fourmonths after exposure. Gross necropsies and histopathology was performed on all animals with particular attention to lung, liver and kidney tissue. The rats and guinea pigs sacraficed after 48 hours demonstrated mild to moderate pulmonary congestion and hemmorhaging. Rats, but not guinea pigs, showed mild to moderate hepatic involvement. Animals sacrificed at four months were unremarkable. Only weekly body weights were recorded. A similar number of animals were used as controls. No deaths were reported in this study.

The results of this study indicate that OBPA produces mild to moderate pulmonary irritation which is reversible after four months.

h. Metabolism

In a study by Olsen et al. (1959, MRID 00026092), OBPA was applied to the skin under occlusive wrap for 24 hours at 0, 100, 200 or 500 mg/kg. Sodium arsenite was applied in a similar manner to the skin as a positive control. The levels of sodium arsenite used in this study were: 10 and 40 mg/kg. A total of six rabbits (one female and five males) of an unspecified strain were used in this study. All animals died in this study, most within 24 hours. The skin of all treated animals was severly burned and hyperemic and endemous. The following items were sampled in this study: liver, blood, feces and urine. The livers from five animals were analyzed for arsenic content: one control, two 100 mg/kg test animals, and two sodium arsenite (10 and 40 mg/kg) animals. Arsenic is not concentrated in the livers of animals treated with sodium arsenite, but accumulates in the livers of animals fed OBPA. Blood levels of arsenic in sodium arsenite were higher than in those animals treated with OBPA. Arsenic is excreted primarily in the feces and secondarily in the urine in animals treated with OBPA. The reverse is true for animals treated with sodium arsenite. While exact clearance times for arsenic could not be determined because urine volumes were not available, the report indicates that arsenic should be eliminated from the body over a two week time period. Because of the damage observed at autopsy and levels observed upon analysis, the target organs for arsenic accumulation from OBPA are the liver and kidney.

As an ancillary part of a dermal LD_{50} determination, Dow (1964, MRID 00024935) administered OBPA (unspecified percent A.I.) as a 20% suspension in dipropylene glycol methyl ether to the skin rabbits (unspecified sex and strain) under occlusive wrap. Exposure occurred for 24 hours. Test animals exhibited severe burns. While the blood, urine, feces and liver tissue were analyzed for arsenic content, the tabulated data were not presented in the report. Data are reported to indicate that detectable levels of arsenic are found in the blood, feces and urine 24 hours after exposure and in the liver 16 days after exosure. An unspecified amount of an aqueous solution of sodium arsenite was applied to the skin of rabbits (unspecified sex and strain) as a positive control. "Marginal concentrations" of arsenic are voided in the urine in "large amounts" within 24 hours after exposure. Liver retention at 16 days was negligible.

Three Duncan-Hartley guinea pigs per dose were administered 300 mg/kg under occlusive bandage for six hours by International Paint Company (1957, MRID 00013591 and Ballantyne, 1978, MRID 05015857). The test compound, technical (unspecified percent A.I.) OBPA was administered as a 20% corn oil suspension. The liver, kidneys and blood of test and three untreated control animals were analyzed for arsenic content. The analytical method used in this study had a limit of detection of 15 micrograms of arsenic, or 50 micrograms of the test material. No arsenic was found in these tissues.

The results of these studies indicate that OBPA is absorbed dermally, resulting also in dramatic skin irritation and necrosis. Because of the damage observed at autopsy, the target organs for arsenic accumulation are the kidney and the liver. Arsenic accumulates in the liver and is cleared from the body after two weeks. The feces and urine are the primary and secondary routes of excretion, respectively.

i. Mutagenicity

Brusick and Weir (1976, MRID 00013644) exposed mouse lyphoma L5178Y cells to technical (99.9%) OBPA. Activated cells were exposed to 0.005, 0.01 and 0.05 ug/ml of active ingredient. Nonactivated cells were exposed to 0.0005, 0.001, 0.005, 0.01 and 0.05 ug/ml of active ingredient. Concentrations greater than 0.1 ug/ml produced cytotoxicity. An initial activation test showed two increases in mutation frequency at dose levels of 0.001 and 0.01 ug/ml, but upon retest at slightly higher concentrations, the test substance showed only slight increases in mutagenicity. The nonactivation test was negative. The results of the initial activation test are considered to be aberrant and the test compound is not considered to be mutagenic under the test conditions.

In a second mutagenicity study performed by Brusick and Weir (1976, MRID 00013647) S. cerevisiae (D-4) and S. typhimurium (TA-98, TA-100, TA-1535, TA-1537 and TA-1538) were exposed to 0.0005, 0.05, 0.5 and 2.5 ug/ml of technical (99.9%) OBPA. The 0.0005 ug/ml dose level was added because of toxicity at the high 2.5 ug/ml dose level. Activated and nonactivated cells were used in this assay. DMSO was used as the solvent in this assay. The results of the tests conducted with both activated and nonactivated cells indicate that the test compound is not mutagenic under the test conditions.

As a second part of a teratology study, Beliles and Makris (1978, MRID GS044007) investigated the mutagenicity of metabolites from Charles River rats which were orally and dermally exposed to OBPA (95.6%). The test animals were given a dermal application of zero, 0.3, 3.0 and 30.0 mg/kg of the test material suspended in corn oil. The animals also received an undetermined amount of OBPA orally because no attempt was made to prevent licking off the material from the test site. Possibly because of the oral ingestion of the test material one mid-dose and all high-dose animals died between day ten through day 14 of gestation. Urine samples were pooled from all dose levels and evaluated for the mutagenic activity of the metabolites according to the method of Durston and Ames. There was no indication of mutagenic activity from either treated or untreated urine in this study.

The results of these studies indicate that technical OBPA is not mutagenic under the test conditions.

j. Teratology

Beliles and Makris (1978, MRID GS044007) investigated the effect of dermal exposure of OBPA (95.6%) on fetuses during the period of organogenesis when administered to 19 pregnant rats per dose. The test material was administered in corn oil at doses of 0.3, 3.0 and 30.0 mg/kg to pregnant female Charles River rats on days six through 15 of gestation. A vehicle control group was included in the study. The test solution was applied to the ventral cervical and thoracic region of the animals. Occlusive wrap or restrainers were not used during this study. The failure to use this wrap and/or restrain the animals resulted in the possible ingestion of the compound by the animals as evidenced by the fact that one mid-dose and all high dose rats died or were in moribund condition between days ten and 14 of gestation. Gross necropsy of treated animals reveal signs of irritation that would be expected with this compound. The fact that ingestion of this compound occurred during the study compromises the value of this study as an estimate of the teratogenic potential of OBPA from dermal exposure. Despite this deficiency, this study can be used to estimate the teratogenic potential of OBPA. Because each animal may have ingested differing amounts of the test material, the exact dosage for each animal can not be estimated in this study.

No evidence of compound-related teratogeicity, variation in sex ratio, or inhibition of fetal development was revealed in this study. While there is evidence of fetal toxicity in the mid-dose group, the distribution of resorptions suggest that the test material was not exerting a significant fetotoxic effect. An NOEL of 0.3 mg/kg can be estimated for teratogenicity, embryotoxicity and fetotoxicity.

2. End-Use Products

a. Acute Oral Toxicity

1) Durotex 7599 (2.0% A.I.)

Two male and two female albino rats per dose were administered a 25% w/v solution of Durotex 7599 in corn oil by Kohn et al. (1968, MRID 00024953). The dose levels in this study were 900, 1350, 2025, and 3038 mg/kg. Gross necropsy showed the survivors to be unremarkable, while the decedents demonstrated hyperemic lungs, stomach and intestines. The LD_{50} is 1650 mg/kg and places this product into toxicity category III.

2) Durotex 7603 (2.0% A.I.)

The oral toxicity of Durotex 7603 was determine by WARF (1976, MRID GS044057). Six male Sprague-Dawley rats were administered, by gavage, a single dose containing either 1000, 2000, or 5000 mg/kg of the test material. The LD_{50} is reported to be between 1000 and 2000 mg/kg, placing this material into toxicity category III.

3) Vinyzene BP-5 (1.0% A.I.)

WARF (1971, MRID 00013631) administered Vinyzene BP-5 at two dose levels (2,000 and 4,000 mg/kg) to six Sprague-Dawley male rats per dose by gavage. No grosslynecropsy or histopathology was performed on either the survivors or decedents. The LD_{50} for this product is between 2,000 and 4,000 mg/kg and places this product into toxicity category III.

4) Vinyzene BP-5-2 (1.0% A.I.)

In a study performed by WARF (1973, MRID 00013610), male Sprague-Dawley rats were administered 1, 2, 5 or 10 ml/kg of BP-5-2 by gavage. In a separate study by WARF (1973) (MRID 00013610), female Sprague-Dawley rats were administered 1, 2 or 5 ml/kg of BP-5-2 by gavage. No controls were used in either study and the reaction to the test material was measured only as number of deaths per dose. No gross necropsy or histopathology was performed on the animals. The acute oral LD_{50} for BP-5-2 in both male and female test animals is between 1 and 2 ml/kg and places this product into toxicity category I.

5) Vinyzene BP-5-3-STL (unspecified % A.I.)

Six rats per dose were administered 0.5, 1.0, 3.0 or 5.0 ml/kg of the test compound by WARF (1974, MRID 00023384). The LD_{50} of Vinyzene BP-5-3-STL to male and female Sprague-Dawley albino rats was between 0.5 to 1.0 ml/kg and places this product into toxicity category III.

6) Vinyzene SB-1 (5.0% A.I.)

In a study performed by WARF (1975, MRID 00013629), six male Sprague-Dawley rats were administered 5, 10 or 20 ml/kg of Vinyzene SB-1 in the feed (1:4). No controls were used and no gross necropsy or histopathology was performed on the animals. The acute oral LD_{50} for SB-1, as tested, is in excess of 20 ml/kg and places this product into toxicity category IV.

WARF (1976, MRID 00013630) determined the acute oral toxicity of Vinyzene SB-1by feeding a single dose of a mixture of the test compound and laboratory chow (1:3) to six Sprague-Dawley rats. No gross necropsy or histopathology was performed on any of the test animals. The single dose LD_{50} of the test compound is greater than 20 gm/kg, placing this product into toxicity category IV.

7) Vinyzene SB-5-2-PPG (unspecified % A.I.)

Gordon et al. (1977, MRID 00013651) administered Vinyzene BP-5-2-PPG to Charles River rats at the following dose levels: 1000, 1470, 2150, 3160, 4640, 6810 and 10000 mg/kg. Four male rats per dose were used in this test. Gross necropsies showed that the survivors were unremarkable. Decedents showed (1) vascular constriction in the brain, stomach and ceacum, (2) pale lungs and liver, and (3) distension of the stomach and intestine by red or yellow viscous material. The oral LD_{50} of this product is 1,470 mg/kg and places this product into toxicity category III.

8) Vinyzene SB-8/12.5D (unspecified % A.I.)

In a study performed by WARF (1977, MRID 00013660), ten male and ten female New Zealand albino rabbits were administered a single 20 mg/kg dose of Formulated SB-8/12.5D by gelatin capsule. No deaths were reported in this study and the LD_{50} is reported to be in excess of 20 mg/kg. No pharmacologic signs were noted in any of the animals and gross necropsy revealed no remarkable alterations. The results of this study place this material into toxicity category IV.

9) Vinyzene SB-8 (25.0% A.I.)

In another study performed by WARF (1977, MRID 00013661), ten male and ten female New Zealand albino rabbits were administered a single 20 mg/kg dose of

Vinyzene SB-8 (25% A.I.) by gelatin capsule. No deaths were reported in this study and the LD_{50} is reported to be in excess of 20 mg/kg. No pharmacologic signs were noted in any of the animals and gross necropsy revealed no remarkable alterations. The results of this study place this material into toxicity category IV.

10) Vinyzene SB-8/25 (unspecified % A.I.)

WARF (1977, MRID 00013662) administered a single 20 mg/kg dose of Formulated SB-8/25 by gelatin capsule to ten male and ten female New Zealand albino rabbits. No deaths were reported in this study and the LD_{50} is reported to be in excess of 20 mg/kg. No pharmacologic signs were noted in any of the animals and gross necropsy revealed no remarkable alterations. The results of this study place this material into toxicity category IV.

11) Vinyzene SB-8/25D (unspecified % A.I.)

In another study performed by WARF (1977, MRID 00013663), ten male and ten female New Zealand albino rabbits were administered a single 20 mg/kg dose of Formulated Product SB-8/25 D by gelatin capsule. No deaths were reported in this study and the LD_{50} is reported to be in excess of 20 mg/kg. No pharmacologic signs were noted in any of the animals and gross necropsy revealed no remarkable alterations. The results of this study place this material into toxicity category IV.

12) Vinyzene SB-1 (40 Mesh) (5.0% A.I.)

WARF (1977, MRID GS044060) dosed six male Sprague Dawley rats per dose with 5000 and 10,000 mg/kg by gavage. The test material (Vinylzenz SB-1, 40 mesh) was administered as a 25% corn oil solution. Gross necropsies were unremarkable except for one low dose animal which had abcessed lobes of the lung. The LD_{50} is reported as 10,000 mg/kg, placing this material into toxicity category IV.

13) Fungicidal Additive (5.0% OBPA)

Hobbs (19??, MRID GS044075) administered 0.1, 1.0 and 10.0 ml/kg of a fungicidal additive containing 5% OBPA to two rats (unspecified sex and strain) per dose. No deaths occurred at the low dose and all animals died at the 1.0 and 10.0 ml/kg dose. Decedents exhibited necrosis of the gastrointestinal tract, moderate kidney pathology (unspecified), depression, diarrhea and diuresis. The LD_{50} is between 0.1 and 1.0 ml/kg, placing this material into toxicity category III.

In another study to determine the toxicity of a Dow Corning bathtub caulking compound containing 1% OBPA, Hobbs (19??, MRID GS044076) administered the test substance to 2 rats (unspecified sex and strain) for each of the following doses: 0.5, 1.0, 2.0 and 4.0 ml/kg. No deaths occurred and survivors exhibited initial depression and weight loss. All animals recovered after two weeks. The LD_{50} is in excess of 4.0 ml/kg, placing the test substance into toxicity category III.

14) Miscellaneous

Powers (1968, MRID 00023386) administered 5,000 and 10,000 mg/kg of Test Material 2473-353-008-8 (unspecified percent A.I.) to male and female Charles River rats (unspecified number of animals per dose). The test material was administered in Karo syrup over a 24 to 48 hour test period. No deaths or toxic sign were reported. Body weights were apparently recorded but not reported. No remarkable findings were reported at gross necropsy. The maximum tolerated dose was reported to be greater than 10,000 mg/kg of the test material.

Hobbs (19??, MRID GS044025) administered an experimental bathtub caulking compound, containing a fungicidal additive with 80 ppm arsenic, to rats (unspecified sex and strain). Two animals per dose were administered 1000 or 10,000 mg/kg of the test material. Only one high dose animal died from ingestion of the test material. The LD_{50} is estimated to be between 1000 and 10,000 mg/kg, placing this material into toxicity category IV.

Hobbs (19??, MRID GS044077) attempted to determine the oral toxicity of a caulking compound. An experimental bathtub caulking compound, containing a fungicidal additive at doses of 5000 and 10,000 mg/kg, was administered to one male and one female rat (unspecified strain) per dose. The test material contained 80 ppm arsenic. No animals died from the test material. No necropsies or histopathology was performed on the animals. The LD_{50} was determined to be in excess of 10,000 mg/kg, placing this material into toxicity category IV.

In a study to determine the toxicity of Dow Corning 780 Building Sealant (unspecified % A.I.), Hobbs (19??, MRID GS044078) administered the test material to two male and two female rats per dose (unspecified strain). The test material, which contained 80 ppm of arsenic derived from the fungicidal additive, was administered at 5000 and 10,000 mg/kg. Two high dose animals died from the test material and none died in the low dose group. The LD_{50} is probably greater than or equal to 10,000 mg/kg, placing this material into toxicity category IV.

15) Summary of Acute Oral Toxicology for End-Use Products

Formulated products containing OBPA generally possess a low order of toxicity, ranging from Toxicity category IV to III. Only Vinyzene BP-5-2 possesses a high order of acute oral LD_{50} of between 1 and 2 ml/kg, placing this material into toxicity category I.

b. Acute Dermal Toxicity

1) Durotex 7599 (2.0% A.I.)

Two male and two female albino rats per dose were administered Durotex 7599 under occlusive wrap for 24 hours by Kohn et al. (1968, MRID 00024953). The dose levels in this study were 2025, 3038, 4556, and 6834 mg/kg. The skin of all animals was unabraded during the test. Reactions by all animals included erythema, edema, anorexia, generalized weakness and drying of the skin at the site of application. Decedents also exhibited hyperemic lungs, enlarged spleen and thickening of the skin at the application site. The dermal LD_{50} is 4560 mg/kg and places this product into toxicity category III.

2) Durotex 7603 (2.0% A.I.)

WARF (1976, MRID GS044057) determined the dermal toxicity of Durotex 7603 by dosing six male rabbits (unspecified strain) to 4000 and 8000 mg/kg under occlusive wrap for 24 hours. Two of the high dose animals died within four days after application. The application site of the surviving high dose animal was defatted and crusty in appearance. The LD_{50} was estimated to be between 4000 to 8000 mg/kg, placing this compound in toxicity category III.

3) Vinyzene BP-5 (1.0% A.I.)

Six male rabbits (unspecified strain) per dose were administered 4, 8, and 12 ml/kg of Vinyzene BP-5 by WARF (1971, MRID 00013631). No gross necropsy or histopathology was performed on either the decedents or survivors. The dermal LD_{50} for this product is between 4 and 8 ml/kg and places this product into toxicity category III.

WARF (1973, MRID 00013610) administered 2, 4 or 8 ml/kg of BP-5-2 under occlusive wrap to six male rabbits (unknown strain). No controls were used in this study and the reaction to the test material was measured only as number of deaths per dose. No gross necropsy or histopathology was performed on the animals. The dermal LD_{50} for BP-5-2 in male test animals is between 2 and 8 ml/kg, placing this product into toxicity category III.

4) Vinyzene BP-5-3-STL (unspecified % A.I.)

Two male rabbits per dose (strain unspecified) were administered doses of 1, 2 or 4 ml/kg of Vinyzene BP-5-3-STL under occlusive wrap for 24 hours. The skin of all animals was dry, hard and wrinkled after administration of the test material. The acute dermal LD_{50} in this study, performed by WARF (1974, MRID 00023384), was between 1.0 and 2.0 ml/kg, placing this compound into toxicity category III.

5) Vinyzene SB-1 (5.0% A.I.)

WARF (1975, MRID 00013629) administered 2000, 4000 or 8000 mg/kg of Vinyzene SB-1 under occlusive bandage to six male rabbits (unknown strain). No controls were used in this study and the reaction to the test material was measured only as number of deaths per dose. No gross necropsy or histopathology was performed on the animals. The acute dermal LD_{50} for Vinyzene SB-1 in male test animals is greater than 8000 mg/kg and places this product into toxicity category III.

WARF (1975, MRID 00013636) performed a single dose determination of the dermal toxicity of Vinyzene SB-1. 20.5 mg of the test compound was applied to the skin of three male and three female New Zealand white rabbits under an occlusive bandage for 24 hours. The test material was applied to patches of skin which were either abraded and intact. No irritation was produced at 24 and 72 hours after application and gross necropsy showed no remarkable changes in the animals. One death occurred 11 days after application of the test compound. The LD_{50} for this compound is greater than 20.5 mg/kg and places this product into toxicity category IV.

WARF (1976, MRID 00013630) administered a single dose of 8000 mg/kg of Vinyzene SB-1 to four rabbits (unspecified sex and strain) under occlusive bandage for 24 hours. No gross necropsy or histopathology was performed. The LD_{50} was determined to be greater than 8000 mg/kg, placing this compound into toxicity catagory III.

6) Vinyzene SB-5-2-PPG (unspecified % A.I.)

Two New Zealand albino rabbits per dose were administered 1,000 or 2,000 mg/kg of Vinyzene BP-5-2-PPG under occlusive wrap for 24 hours by Gordon et al. (1977, MRID 00013652). The test material was applied to patches of both abraded and intact skin. No gross necropsy or histopathology was performed in this test. The dermal LD_{50} in this study is greater than 2,000 mg/kg and places this product into toxicity category III.

7) Vinyzene SB-8/12.5D (unspecified % A.I.)

Four male and four female New Zealand albino rabbits were exposed to a single 20,000 mg/kg dose under occlusive wrap by WARF (1978, MRID 00013660). Exposureto Formulated SB-8/12.5 D resulted in no pharmacological signs. Necropsy of the test animals revealed kidneys with mild petechial hemmorrhaging. The dermal LD_{50} is estimated to be in excess of 20,000 mg/kg, placing this compound into toxicity category IV.

8) Vinyzene SB-8 (25.0% A.I.)

Three male and three female New Zealand albino rabbits were exposed to a single 20,000 mg/kg dose under occlusive wrap by WARF (1978, MRID 00013661). Exposure to Vinyzene SB-8 (25% A.I.) resulted in no pharmacological signs. Necropsy of the test animals revealed kidneys with mild petechial hemorrhaging and lungs which were red in color. The dermal LD_{50} is estimated to be in excess of 20000 mg/kg, placing this compound into toxicity category IV.

9) Vinyzene SB-8/25 (unspecified % A.I.)

Four male and four female New Zealand albino rabbits were exposed to a single 20,000 mg/kg dose under occlusive wrap by WARF (1978, MRID 00013662). Exposure to the formulated product SB-8/25 resulted in no pharmacological signs. Necropsy of the test animals revealed kidneys with extensive petechial hemorrhaging and lungs which were red in color. The dermal LD_{50} is estimated to be in excess of 20,000 mg/kg, placing this compound into toxicity category IV.

10) Vinyzene SB-8/25D (unspecified % A.I.)

Four male and four female New Zealand albino rabbits were exposed to a single 20000 mg/kg dose under occlusive wrap by WARF (1978, MRID 00013663). Exposure to the formulated product SB-8/25 D resulted in no pharmacological signs. Necropsy of the test animals revealed kidneys with extensive petechial hemorrhaging and lungs which were red in color. The dermal LD_{50} is estimated to be in excess of 20,000 mg/kg, placing this compound into toxicity category IV.

11) Fungicidal Additive (5.0% OBPA)

Hobbs (19??, MRID GS044075) administered 2000 mg/kg of a fungicidal additive containing 5% OBPA to two rabbits (undetermined sex and strain). The test compound was possibly administered under occlusive wrap, possibly for 24 hours. No notes were made on the one decedent, but the surviving animal showed significant weight loss and CNS depression. The results of this study possibly place this compound into toxicity category II.

12) Miscellaneous

In another study by Hobbs (19??, MRID GS044077) six rabbits (unspecified sex and strain) were dosed with 2000 mg/kg of an experimental bathtub caulking compound. This compound contained a fungicidal additive with 80 ppm of arsenic. Three animals had intact skin and three had abraded skin. All animals survived treatment. No necropsy or histopathology was performed on any animal. No animals died from the treatment and the results of this study place this compound into toxicity category III.

In another study performed by Hobbs (19??, MRID GS044078), Dow Corning 780 Building Sealant (unspecified % A.I.) was administered to six male animals, possibly rabbits (unspecified sex), at a rate of 2000 mg/kg. Three animals had abraded and three intact skin. No deaths resulted from treatment with the material. The LD_{50} is estimated to be in excess of 2000 mg/kg, placing this material into toxicity category III.

13) Summary of Acute Dermal Toxicity of End-Use Products

Formulated products containing OBPA generally possess a low order of toxicity, falling within toxicity categories II to III. The Fungicidal Additive with 5.0% OBPA differs from the other formulated products in that it possesses a moderate order of toxicity, falling within toxicity category II.

c. Acute Inhalation Toxicity

Data on the acute inhalation toxicity of end-use products containing OBPA are available for only one end-use product, a fungicidal additive containing 5.0% OBPA.

Hobbs (19??, MRID GS044075) exposed five rats (unspecified sex and strain) to asaturated atmosphere containing 6.82 mg/L of a fungicidal additive containing 5% OBPA. No information on the test conditions, except for an exposure time of 7 hours, was available. No animals died from exposure to the test material and only heavy salivation was the only toxic sign during exposure. The LC_{50} is in excess of 6.82 mg/L, placing this compound into toxicity category III.

d. Primary Eye Irritation

1) Durotex 7599 (2.0% A.I.)

Kohn et al. (1968, MRID 00024956) tested the eye irritation potential of Durotex 7599 by instilling 0.1 ml into the eyes of five New Zealand albino rabbits. The study does not mention whether the compound was washed from any of the eyes. Instillation of the test compound resulted in corneal opacity and a 72 hour Draize score of 57.4, placing this product into toxicity category I.

WARF (1976, MRID 00013630) instilled 0.1 ml of Durotex 7599 into the eyes of five New Zealand albino rabbits (unspecified sex). The study did not employ an eye wash. Exposure to the test compound resulted in irritation of the cornea, iris and conjunctivae with a Draize score of 55.4 out a total possible score of 110 at 7 days. The results of this study place this material into toxicity category I.

2) Durotex 7603 (2.0% A.I.)

The eye irritation potential of Durotex 7603 was determined by WARF (1976, MRID GS044057). Durotex 7603 is a fabric containing 1000 ppm OBPA. The eyes of six New Zealand albino rabbits were instilled with 0.1 gm of the test material. The test material produced corneal opacity and redness, chemosis and discharge. The primary eye irritation score is 32.0 out of 110, placing this material into the toxicity category I.

3) Vinyzene BP-5 (1.0% A.I.)

WARF (1975, MRID 00013632) studied the eye irritation potential of Vinyzene BP-5by placing 0.1 ml of the test compound into the eyes of six albino rabbits (unspecified sex). The rabbit eyes were not washed in this study. Exposure to the test compound resulted in Draize score of zero out of a total possible score of 110 at 72 hours, placing this product into toxicity category IV.

This test is considered to be invalid because the results conflict with the known corrosiveness of OBPA to the eye and, more importantly, the results of the primary skin irritation test (see below).

4) Vinyzene BP-5-2 (1.0% A.I.)

WARF (1975, MRID 00013636) studied the eye irritation potential of Vinyzene BP-5-2 by placing 0.1 ml of the test compound into the eyes of six albino rabbits (unspecified sex). The study does not mention whether the compound was washed from any of the eyes. Exposure to the test compound resulted in Draize score of 4.0 out of a total possible score of 110 at 72 hours, placing this product into toxicity category III.

This test is considered to be invalid because the results conflict with the known corrosiveness of OBPA to the eye and, more importantly, the results of the primary skin irritation test (see below).

5) Vinyzene SB-5-2-PPG (unspecified % A.I.)

WARF (1977, MRID 00013653) instilled 0.1 ml of Vinyzene BP-5-2-PPG into the eyes of six white New Zealand rabbits (unspecified sex). The study does not mention whether the compound was washed from any of the eyes. Exposure to the test compound resulted in a Draize score of 5.33 out of a total possible score of 110 at 72 hours, placing this product into toxicity category III.

This test is considered to be invalid because the results conflict with the known corrosiveness of OBPA to the eye and, more importantly, the results of the primary skin irritation test (see below).

6) Fungicidal Additive (5.0% OBPA)

Hobbs (19??, MRID GS044075) administered an undetermined amount of a fungicidal additive containing 5% OBPA into the eyes of rabbits (unspecified sex, strain and number). Washed and unwashed eyes exhibited severe conjunctivitis and moderate corneal response with essentially no pain. The effects of the material subsided within 7 days. The results of this study place this material into toxicity category II.

7) Bathtub Caulk (1.0% OBPA)

In another study by Hobbs (19??, MRID GS044076), a Dow Corning experimental bathtub caulking compound containing 1% OBPA was instilled into the eye of an undetermined number of rabbits (unspecified sex and strain). Eyes washed after instillation of the test material exhibited moderate conjunctivitis and iritis which subsided within 7 days. Unwashed eyes showed similar effects, but also exhibited a corneal response (unspecified) which subsided within two weeks. The results of this study place the material into toxicity category II.

8) Miscellaneous

Hobbs (19??, MRID GS044025) studied the eye irritation potential of an experimental bathtub caulking material. An undetermined amount of the test material containing a fungicidal additive with 80 ppm arsenic was instilled in the eyes of an undetermined number of rabbits (unspecified sex and strain). Both washed and unwashed eyes exhibited severe pain with slight conjunctival and corneal response (unspecified). The washed eye and unwashed eyes recovered within 2 and 7 days, respectively. The results of this test place the test material into toxicity category IV.

Hobbs (19??, MRID GS044077) instilled an undetermined amount of a bathtub caulking compound containing a fugicidal additive (unspecified % A.I.) into the eyes of six rabbits (unspecified sex and strain). The test material contained 80 ppm of arsenic. Corneal, irital and conjunctival irritation of a minor nature was produced by the test substance. Minor corneal irritation of an unspecified nature persisted through the seventh day. The results of this study place the test material into toxicity category II.

Dow Corning 780 Building Sealant containing 80 ppm of arsenic from a fungicidal additive was tested for eye irritation potential by Hobbs (19??, MRID GS044078). Insillation of a undetermined amount of the test material into the eye of six rabbits (unspecified sex and strain) produced mild chemosis and redness of the conjunctiva of three animals and mild reaction of the the iris (unspecified). All effects subsided by the seventh day. The results of this study place the material into toxicity category III.

9) Summary of Primary Eye Irritation of End-Use Products

Formulated products containing OBPA are moderate to severe irritants (e.g. toxicity categories IV through I). It is not possible to generalize on the eye irritation potential of end-use products because the inert ingredients in these formulations cause the individual products to vary markedly.

e. Primary Skin Irritation

1) Durotex 7599 (2.0% A.I.)

Kohn et al. (1968, MRID 00024953) tested the skin irritation potential of Durotex 7599 by placing 0.5 ml of the test compound, under occlusive wrap, onto the skin of six New Zealand albino rabbits (unspecified sex) for 24 hours. The primary irritation score is 4.98 out of a total possible score of 8, placing this product into toxicity category II.

Kohn et al. (1968, MRID GS044079) tested the irritating properties of a piece of fabric containing Durotex 7599. The test material contained 1,000 ppm of OBPA. The test material was applied to patches of both intact and abraded skin of six New Zealand albino rabbits (unspecified sex) under occlusive wrap for 24 hours. The test material produced no irritation, placing this product into toxicity category IV.

2) Durotex 7603 (2.0% A.I.)

In another study performed by Kohn et al. (1968, MRID GS044033), Durotex 7603 was applied to patches of both intact and abraded skin of six New Zealand albino rabbits (unspecified sex) for 24 hours. The test material is a piece of fabric which contains 1,000 ppm of OBPA. The test material produced no irritation, placing Durotex 7608 into toxicity category IV.

3) Vinyzene SB-1 (40 Mesh) (5.0% A.I.)

WARF (1977, MRID GS044061) administered 0.5 ml of Vinyzene SB-1 (40 mesh) to six albino New Zealand rabbits under occlusive wrap. The test material produced a primary irritation score of 0.5 after 24 hours. The results of this test place this material into toxicity category IV.

4) Vinyzene BP-5 (1.0% A.I.)

WARF (1975, MRID 00013632) studied the skin irritation potential of Vinyzene BP-5 by placing 0.5 ml of the test compound, under occlusive wrap, onto the skin of six albino rabbits (unspecified sex) for 24 hours. Exposure to the test compound resulted in primary irritation score of 6.13 out of a total possible score of 8.0, placing this product into toxicity category I.

5) Vinyzene BP-5-2 (1.0% A.I.)

WARF (1975, MRID 00013636) studied the skin irritation potential of Vinyzene BP-5-2 by placing 0.5 ml of the test compound, under occlusive wrap, onto the skin of six albino rabbits (unspecified sex) for 24 hours. Exposure to the test compound resulted in primary irritation score of 7.0 out of a total possible score of 8.0, placing this product into toxicity category I.

6) Vinyzene SB-5-2-PPG (unspecified % A.I.)

In a second part of an earlier dermal toxicity study by Gordon et al. (1977, MRID 00013652), two New Zealand albino rabbits exposed to 1,000 or 2,000 mg/kg of Vinyzene BP-5-2-PPG under occlusive wrap for 24 hours were graded for primary skin irritation. The test compound produced moderate to severe edema at both doses and moderate erythema at the high dose. The primary skin irritation index of this product is 5.4 out of a total possible score of 8.0, placing this product into toxicity category II.

WARF (1977, MRID 00013653) exposed six white New Zealand rabbits (unspecified sex) to 0.5 ml of Vinyzene BP-5-2-PPG under occlusive wrap for 24 hours. The primary irritation index of this product is 5.58 out of a total possible score of 8.0, placing this product into toxicity category II.

7) Vinyzene SB-8/12.5D (unspecified % A.I.)

In a study performed by WARF (1978, MRID 00013660), six New Zealand albino rabbits (unspecified sex) were exposed to 0.5 gm of formulated SB-8/12.5D under occlusive wrap. The test material was applied to patches of both abraded and intact skin. The primary irritation index was 0.5 out of a total of eight, placing this compound into toxicity category IV.

8) Vinyzene SB-8 (25.0% A.I.)

In a study performed by WARF (1978, MRID 00013661), six New Zealand albino rabbits (unspecified sex) were exposed to 0.5 gm of Vinyzene SB-8 (25% A.I.)under occlusive wrap. The test material was applied to patches of both abraded and intact skin. The primary irritation index was zero out of a total of eight, placing this compound into toxicity category IV.

In another study performed by WARF (1978, MRID 00013663), six New Zealand albino rabbits (unspecified sex) were exposed to 0.5 gm of Vinyzene SB-8 (25% A.I.) under occlusive wrap. The test material was applied to patches of both abraded and intact skin. The primary irritation index was 2.62 out of a total of eight, placing this compound into toxicity category III.

9) Vinyzene SB-8/25 (unspecified % A.I.)

WARF (1978, MRID 00013662) exposed six New Zealand albino rabbits (unspecified sex) to 0.5 gm of Formulated Product SB-8/25 under occlusive wrap. The skin had patches both abraded and intact. The primary irritation index was 1.92 out of a total of eight, placing this compound into toxicity category III.

10) Fungicidal Additive (5.0% OBPA)

Hobbs (19??, MRID GS044075) administered an undiluted fungicidal additive containing 5% OBPA to patches of abraded and intact skin and the ear of rabbits (unspecified sex, strain and number). The compound remained in contact with the skin, possibly under occlusive wrap, for 15 minutes, 1, 2, 4 and 24 hours. Effects rapidly progressed as a function of time from none at 15 minutes, to slight to severe erythema and edema with necrosis, regardless of the initial condition of the skin. The results of this study place the test material into toxicity category I.

11) Bathtub Caulk (1.0% OBPA)

In another study by Hobbs (19??, MRID GS044076), Dow Corning bathtub caulking with 1% OBPA was placed, possibly under occlusive wrap, on the intact and abraded skin and on the ear of rabbits (unspecified sex, strain and number). All test site demonstrated moderate erythema, edema and necrosis. The length of exposure to the material is not mentioned in the report. The results of this study place the test material into toxicity category II.

12) Miscellaneous

Gabriel (1970, MRID 00013603) exposed six albino rabbits (unspecified sex and strain) to 0.5 ml of 3M Sample T-220 (NOMAD Surfacing Material, unspecified percent A.I.) for 24 hours under occlusive wrap. The skin of the test animals was both abraded and intact. No reaction to the compound was observed in this test, placing this material into toxicity category IV.

3M Company (1970, MRID 00013601) exposed six albino rabbits (unspecified strain) to 0.5 ml of 3M Sample T-220 (NOMAD Surfacing Material, unspecified percent A.I.) for 8 hours per day, five days per week for three weeks. The test material was kept in contact with both abraded and intact skin under occlusive wrap. No reaction to the compound was observed in this test, placing this material into toxicity category IV.

Hobbs (19??, MRID GS044025) tested the dermal irritation potential of an experimetal bathtub caulking compound containing an fungicidal additive with 80 ppm arsenic. This compound was repeatedly placed on patches of intact and abraded skin, possibly under occlusive wrap, and the ear of an undetermined number of rabbits (unspecified sex and strain). Three applications of the test material to the ear and two applications to patches of abraded and intact skin resulted in moderate erythema and necrosis followed by formation of a scab. The results of this study place this test material into at least toxicity category III.

Hobbs (19??, MRID GS044077) estimated the dermal irritability of a bathtub caulking compound with a fungicidal additive which contained 80 ppm arsenic. An undetermined number of rabbits (unspecified sex and strain) were exposed to the test material, possibly under occlusive wrap. Administration of the material resulted in a primary irritation score of 2.6 out of a possible score of eight, placing this compound into toxicity category III.

In a study performed by Hobbs (19??, MRID GS044078) on Dow Corning 780 Building Sealant (unspecified percent A.I.), the test material was placed on patches of intact and abraded skin, possibly under occlusive wrap, of rabbits (unspecified sex, strain and number). The test material produced mild erythema and edema to intact and abraded skin. The primary irritation score was 2.1 out of 8, placing this material into toxicity category III.

13) Summary of Primary Skin Irritation of End-Use Products

Formulated products containing OBPA possess a broad range of dermal irritation abilities (e.g. toxicity categories IV through I). It is, therefore, not possible to generalize on the skin irritation potential of end-use products because the inert ingredients in these formulations cause the individual products to vary markedly.

f. Skin Sensitization

1) Durotex 7603 (2.0% A.I.)

Egger and Ison (1976, MRID GS044020) tested Durotex 7603 for its ability to sensitize skin. Durotex 7603 is a fabric containing 1,000 ppm of OBPA. 63 male and female panelists, 58 of whom completed the study, were exposed to Durotex 7603 for 24 hours. A challenge, made 14 days after the initial application, resulted in no reactions. The test material is not considered to be a sensitizing agent.

2) Vinyzene BP-10 (unspecified % A.I.)

WARF (1974, MRID 00023377) tested Vinyzene BP-10 for skin sensitization potential by subcutaneously injecting 0.1 ml of the test compound into ten white male guinea pigs for ten consecutive days. No skin sensitization was observed when the test animals were later challenged with 0.05 ml of the test compound after a two week rest period.

3) Vinyzene SB-1 (5.0% A.I.)

WARF (1976, MRID 00013630) tested Vinyzene SB-1 for skin sensitization potential by injecting 0.1 ml of the test compound subcutaneously into ten male guinea pigs for ten days. The test material was diluted as a 0.01% saline solution. After a two week rest period, the animals were challenged with a 0.05 ml dose of the test compound. No sensitization to the test compound was observed, but slight erythema was present at the test site.

4) Miscellaneous

21 human infants were tested for sensitization to Blue CGT 7730-118-1 and Blue CGT 7730-118-2 (unspecified percent A.I.) by Guillaume et al. (1966, MRID 00024946). Impregnated plastic containing the test compound was applied twice within 24 hours to the skin of infants less than one year old during a one week period. After a one week rest period, the test subjects were challenged with the same test material. There was a minor incidence of mild erythema and slight glazing of the application site. No sensitization was observed.

5) Summary of Skin Sensitization of End-Use Products

Current data indicate that none of the current formulations of OBPA, which were tested, are dermally sensitizing.

h. Subchronic Dermal Toxicity

1) Vinyzene BP-5 (1.0% A.I.)

Cox and Stevens (1979, MRID GS044017) performed a 21 day subchronic dermal study using Vinyzene BP-5. Male and female New Zealand white rabbits were dosed at 0.1, 0.5 or 1.0/0.75 g/kg of body weight. Because of high mortality, the 1.0 g/kg dose was reduced to 0.75 g/kg on the 13th day of this study. A vehicle control group was dosed at 1.0 g/kg of body weight. No other control groups, using either the technical grade of the active ingredient or 0 g/kg of Vinyzene BP-5, were used in this study.

Dermal application of Vinyzene BP-5 over a 21 day period produced toxicity typical of an arsenical (eg. ulcerative dermatitis, capillary fragmentation and muscle degeneration). The test material and treatment conditions (placing animals in stocks) caused dose related deaths, increases in adrenal weights and decreases in body weights which are typical of stress-related reactions. A decrease in spermatogenesis seen in the high dose group is considered to be a stress-related effect of the test material and the testing conditions. This study is not sufficient to determine the hazard associated with Vinyzene BP-5 because of the lack of proper control groups. While this study does not meet the Agency's current testing requirements, a NOEL can be estimated as 0.1 g/kg of body weight for Vinyzene BP-5.

2) Vinyzene BP-10 (unspecified % A.I.)

In a second subchronic dermal study performed with Vinyzene BP-10, WARF (1974, MRID 00023377) administered the test compound in distilled water to New Zealand white rabbits as a 10% and 20% solution. Tween 80, a surfactant, was added to the test mixture to enhance the solubility of the test compound. Except for reduced food consumption and body weights in the high dose female test animals, food consumption and body weight determinations were unremarkable. Organ weights for all test animals were unremarkable, except for the reduced size of high dose females. The results of hematological tests performed prior to initiating the study and at the termination of the study were unremarkable. Gross necropsy of the animals showned compound related exfoliation, thickening and erythema of the epidermis. Histopathological examination of control and treatedmales revealed small, atrophic, degenerated testes. The researcher determined that the testicular effect was not compound related.

3) Summary of Subchronic Dermal Toxicity of End-Use Products

Continued dermal application produced irritation consistent with the corrosive nature of this material, and toxicity typical of an arsenical.

B. HUMAN HAZARD ASSESSMENT

The use of OBPA is limited to incorporation of formulated OBPA into impregnated materials such as plastics and caulking material to protect the treated materials from microbial attack.

Potential exposure to OBPA is limited to 1) The manufacture of technical or formulated OBPA or OBPA treated materials and 2) the use of the treated materials.

1. Hazard From Manufacture and Use of OBPA

a. Summary of Toxic Effects

1) Acute Effects

a) Manufacturing-Use OBPA

Currently available data indicate that technical OBPA is acutely toxic by the oral and dermal routes. While not acutely toxic by the inhalation route, OBPA possesses sufficient irritating properties which preclude prolonged human exposure. The available data indicate that the technical material is not dermally sensitizing. Technical OBPA is very irritating to both the eyes and the skin. The Agency has determined that the use of goggles and gloves and the use of "closed systems" during the manufacturing process are sufficient to eliminate irritation from future manufacturing-use products containing this chemical.

b) End-Use OBPA

Currently available data on formulated products containing OBPA generally indicate these products possess a low order of acute toxicity by the oral and dermal routes. Little information is available on the acute inhalation toxicity of formulated products. Formulated products are generally very irritating to the eye, are a minor skin irritant and are not dermally sensitizing. The Agency has determined that the use of goggles and gloves and the use of "closed systems" during the manufacturing process are sufficient to eliminate irritation and irritation hazard from registered end-use products containing this chemical.

2) Chronic Effects

The limited data available to assess the effects of chronic exposure to CBPA indicate that (1) this material and its metabolites are not mutagenic, (2) this material possesses a subchronic toxicity and metabolism somewhat similar to arsenic which also indicates a high margin of safety to the user of products containing this chemical, and (3) that this material is not teratogenic, fetotoxic or embryotoxic. No other chronic toxicity data are available.

b. Summary of Exposure

Production of CBPA technical, formulated products, and impregnated materials is presently performed in closed systems by virtually all registrants because of the nature of CBPA as an eye irritant. Hence, there is little to no exposure toCBPA during the manufacturing process.

c. Hazard Assessment

Based on the extremely low potential for exposure, no human hazard is expected from the production and use of CBPA if goggles and gloves are used during a "closed system" manufacturing process.

2. Hazard From Exposure to CBPA Treated Materials

Based on the low exposure to CBPA, leaching from treated materials in relation to the levels at which acute toxic effects were identified in formulated products, no acute toxic effects are expected from exposure to currently registered CBPA treated materials. The lack of mutagenic, teratogenic, fetotoxic or embryotoxic effects for the formulated product indicate that such effects are not likely from materials treated with CBPA. Therefore, no human hazard is expected to result from the exposure to finished products treated with CBPA.

C. SUMMARY OF DATA GAPS

No additional toxicology data are required to support the existing uses of CBPA. If new uses are proposed that might result in significant increases in human exposure, detailed exposure data and/or chronic toxicity testing may be required.

VII. RESIDUE CHEMISTRY

An allowable residue level (tolerance) for specific chemicals is determined by the Agency for the commodities on which they may occur. Since no 10,10'-oxybis-10H-phenoxarsine (OBPA) product is registered for use on food or feed crops, its use should not result in such residues. Therefore, there are no residue chemistry data for this chemical.

VIII. ECOLOGICAL EFFECTS

A. Ecological Effects Profile
B. Ecological Effects Hazard Assessment
C. Summary of Data Gaps

A. ECOLOGICAL EFFECTS PROFILE

The end-use products of OBPA are additives used primarily for preserving fabrics and plastic materials against attack by fungi and bacteria. These products are not associated with uses which would effect nontarget organisms. Therefore, fish and wildlife toxicity data are not required to be submitted or cited. The Agency has, however, reviewed some ecological effects data on OBPA. The results are presented in Table 2.

B. ECOLOGICAL EFFECTS HAZARD ASSESSMENT

The above data indicate that manufacturing-use products are very highly toxic and end-use products are only slightly less toxic to aquatic organisms. The tested end-use product possesses a very low order of toxicity to avian species. Despite this toxicity, the uses of this compound preclude release into the environment. Therefore, no hazard to fish and wildlife is expected from the existing uses of OBPA.

C. SUMMARY OF DATA GAPS

No further fish and wildlife toxicity data are required.

Table 2

ECOLOGICAL EFFECTS DATA

Species	Test	Formula	Results	Citation
Daphnia	48-hr LC_{50}	Technical 99.0% Active OBPA	4.8 ppb	Browne, 1980, MRID 00030657
Grass Shrimp	96-hr LC_{50}	Technical 95.6% Active OBPA	50 ppb	Heitmuller, 1979, MRID 00030656
Bluegill	96-hr LC_{50}	Technical 95.6% Active OBPA	8.0 ppb	Buccafusco, 1977, MRID GS044009
Rainbow Trout	96-hr LC_{50}	Technical 95.6% Active OBPA	3.5 ppb	Buccafusco, 1977, MRID GS044009
Sheepshead Minnow	96-hr LC_{50}	Technical 95.6% Active OBPA	8.0 ppb	Heitmuller, 1980, MRID 00030658
Bluegill	96-hr LC_{50}	Formulation 5.0% Active OBPA	1800 ppm	Bentley, 1976, MRID 00013641
Rainbow Trout	96-hr LC_{50}	Formulation 5.0% Active OBPA	560 ppm	Bentley, 1976, MRID 00013641
Bobwhite Quail	Acute LC_{50}	Formulation 5.0% Active OBPA	>10,000 ppm	Fink, 1976, MRID 00013648
Mallard Duck	Acute LD_{50}	Formulation 5.0% Active OBPA	>10,000 mg/kg	Fink, 1976, MRID 00013649
Bluegill	96-hr LC_{50}	Formulation 3.0% Active OBPA	0.210 ppm	Lee and Regel, 1974, MRID GS044067

Table 2, continued

ECOLOGICAL EFFECTS DATA

Species	Test	Formula	Results	Citation
Rainbow Trout	96-hr LC_{50}	Formulation 3.0% Active OBPA	0.125 ppm	Lee and Regel, 1974, MRID GS044067
Bluegill	96-hr LC_{50}	Formulation 2.0% Active OBPA	0.350 ppm	WARF, 1973, MRID 00013611
Rainbow Trout	96-hr LC_{50}	Formulation 2.0% Active OBPA	0.200 ppm	WARF, 1973, MRID 00013611

IX. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

A. CONTENT OF BIBLIOGRAPHY

This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into two sections: (1) citations in alphabetical order that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registration under the standard, (2) citations in alphabetical order judged to be inadequate or not relevant to support registration and therefore not considered part of the data base for this standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

B. UNITS OF ENTRY

The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

C. IDENTIFICATION OF ENTRIES

The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph D(4)(d) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by an eight-character temporary identifier. This is also to be used whenever a specific reference is needed.

D. FORM OF THE ENTRY

In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

1. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

2. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

3. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

4. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

   (a) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (b) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (c) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(d) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD ALPHABETICAL BIBLIOGRAPHY
Section 1: Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

MIRD	CITATION
GS044002	Anspach, P.S. (1977) Acute Toxicity and Irritation Studies of OBPA (95.6%). (Unpublished study prepared by Hill Top- Toxicology Division of Hill Top Testing Services, Inc.)
00013643	Anspach, P.S. (1977) Acute Toxicity and Irritation Studies of 99.9% 10/10'-Oxybisphenoxarsine: 76-990-21. (Unpublished study received Feb 16, 1977 under 2829-115; prepared by International Bio-Research, Inc., submitted by Ventron Corp., Beverly, Mass.; CDL:228087-B)
GS044004	Babish, J.G. (1978) The Acute Dermal Toxicity (LD_{50}) of OBPA with Sprague-Dawley Rats. (Unpublished study prepared by Food and Drug Research Laboratories, Inc.)
05015857	Ballantyne, B. (1978) The comparative short-term mammalian toxicology of phenarsazine oxide and phenoxarsine oxide. Toxicology 10(4):341-461.
GS044007	Beliles, R.P.; Makris, S.L. (1978) Teratology Study in Rats. 10-10'-Oxybisphenoxarsine: LBI Project No. 20816. (Unpublished study prepared by Litton Bionetics, Inc.)
00013641	Bentley, R.E. (1976) Acute Toxicity of Vinyzene [sic] SB-1 to Bluegill (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*). (Unpublished study received Feb 5, 1976 under 2829-115; prepared by EG&G, Bionomics, submitted by Ventron Corp., Beverly, Mass.; CDL:226171-V)
00030657	Brown, A.M.; (1980) The Acute Toxicity of 10,10'-Oxybisphenoxarsine to the Water Flea *Daphnia Magna* Straus: UCES Project No. 11507-57-02. (Unpublished study received May 29, 1980 under unknown admin. No.; prepared by Union Carbide Corp., submitted by Thiokol Corp., Ventron Div., Danvers, Mass., CDL:242904-D)
00013647	Brusick, D.; Weir, R.J. (1976) Mutagenicity Evaluation of 10,10'-Oxybisphenoxarsine (Technical): Final Report: LBI Project No. 2547. (Unpublished study received Jul 15, 1976 under 2829-115; prepared by Litton Bionetics, Inc., submitted by Ventron Corp., Beverly, Mass.; CDL:228091-A)

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MRID	CITATION
00013644	Brusick, D.J.; Weir, R.J. (1976) Mouse Lymphoma Mutagenicity Evaluation of 10,10'-Oxybisphenoxarsine: Final Report: LBI Project No. 2548. (Unpublished study received Nov 9, 1976 under 2829-115; prepared by Litton Bionetics, Inc., submitted by Ventron Corp., Beverly, Mass.; CDL:228088-A)
GS044009	Buccafusco, R.J. (1977) Acute Toxicity of OBPA to Bluegill and Rainbow Trout. (Unpublished study prepared by EG and G Bionomics)
GS044011	Cadmus, E.L. (1973a) Extractability of Vinyzene BP-5, Laboratory Report submitted by Ventron Corporation, Beverly, MA, Mar 30.
GS044012	Cadmus, E.L. (1973b) Extractability of Vinyzene BP-10 from Light-gauge Plasticized Vinyl Film used as Baby Pants' Material, Laboratory Report submitted by Ventron Corporation, Beverly, MA, Oct 1.
GS044017	Cox, G.E.; Stevens, K.R. (1979) Dermal and Systemic Toxicity Study of Vinyzene BP-5 Following Repetitive Dermal Application over a 21-Day Period to the Intact and Abraded Skin of New Zealand Albino Rabbits. Report No. 5801 of Food and Drug Research Lab, Inc., Jan 5.
00024935	Dow Chemical Company (1964) Toxicological Properties of 10,10'-Oxybisphenoxarsine. (Unpublished study received Nov 2, 1964 under unknown admin. No.; submitted by ?; CDL:121914-A)
00026094	Dow Chemical Company, U.S.A. (1965) Chemical and Physical Properties of Dow Fungicide SA-546. (Unpublished study received Feb 17, 1965 under unknown admin. No.; CDL:119577-A)
GS044020	Egger, D.; Ison, A. (1976) Reported Insult Patch Test of Two Fabric Samples. (Unpublished study received ? under an unknown admin. no.; prepared by Hill Top Research, Div. of Hill Top Testing Services, Inc.)
00013649	Fink, R. (1976) Final Report: Acute Oral LD_{50}—Mallard Duck: Project No. 121-107. (Unpublished study received on unknown date under 2829-115; prepared by Truslow Farms, Inc. in cooperation with Maryland, Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Ventron Corp., Beverly, Mass.; CDL: 228092-B)

MRID	CITATION
00013648	Fink, R. (1976) Final Report: Eight-Day Dietary LC_{50}--Bobwhite Quail: Project No. 121-105. (Unpublished study received on unknown date under 2829-115; prepared by Truslow Farms, Inc. in cooperation with Maryland, Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Ventron Corp., Beverly, Mass.; CDL:228092-A)
00024936	Frantz, G.C.; Shrader, S.A. (1959) Results of a 35-day Dietary Feeding Study of 10,10'-Oxybisphenoxarsine to Rats. (Unpublished study received Nov 2, 1964 under unknown admin. No.; prepared by Dow Chemical Co. in cooperation with Biochemical Research Laboratory, submitted by ?; CDL:121914-B)
00013603	Gabriel, K.L. (1970) Primary Skin Irritation Study. (Unpublished study received Nov 15, 1971 under 10350-3; prepared by Biosearch, Inc., submitted by 3M Co., St. Paul, Minn.; CDL: 230572-D)
00013652	Gordon, E.B.; Rene, A.A.; Weir, R.J. (1977) Final Report: Acute Dermal Toxicity Study in Rabbits: LBI Project No. 2773. (Unpublished study received Jun 12, 1977 under 2829-96; prepared by Litton Bionetics, Inc., submitted by Ventron Corp., Beverly, Mass.; CDL:230703-B)
00013651	Gordon, E.B.; Rene, A.A.; Weir, R.J. (1977) Final Report: Acute Oral Toxicity in Rats: LBI Project NO. 2772. (Unpublished study received Jun 12, 1977 under 2829-96; prepared by Litton Bionetics, Inc., submitted by Ventron Corp., Beverly, Mass.; CDL: 230703-A)
00024946	Guillaume, R.O.; Elsea, J.R.; Ede, M. (1966) Patch Test of Films Blue CGT Production, 7730-118-2, and 7730-118---1 in Infants: Q-316. (Unpublished study received Sep 15, 1969 under 8730-1; prepared by Hill Top Research, Inc., submitted by Herculite Products, Inc., New York, N.Y.; CDL:100580-A)
GS044023	Hamilton, N.F. (1978) Laboratory Report Evaluating the Diffusive Properties of New Biocides ATV-129, C-10545, and RH-893 in Three Polymer Systems Compared to OBPA. Test 78-49 Part 1. (Unpublished study received ? under an unknown admin. no.; prepared by Ventron Corp., Beverley, MA)
GS044024	Hamilton, N.F. (1978) Efficacy Study of PVC Films Containig OBPA: Test 78-49 Part 1B. (Unpublished study received ? under an unknown admin. no.; prepared by Ventron Corp., Beverley, MA)

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MRID	CITATION
00030656	Heitmuller, T. (1979) Acute Toxicity of 10,10'-Oxybisphenoxarsine (OBPA) to Grass Shrimp (Palaemonetespug:o): Report No. BP-79-11-167. (Unpublished study received May 29, 1980 under unknown admin. No.; prepared by EG&G, Bionomics, submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:242904-A)
00030658	Heitmuller, T. (1980) Acute Toxicity of OBPA (10,10'-Oxybisphenoxarsine) to Sheepshead Minnows (Cyprinodon variegatus): Report No. BP-80-2-30. (Unpublished study received May 29, 1980 under unknown admin. No.; prepared by EG&G, Bionomics, submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:242904-E)
GS044025	Hobbs, E. (1977) Acute Toxicologic Properties of EXP Bathtub Caulk. (Unpublished study received ? under and unknown admin. no.; prepared by Dow Corning Corp.)
GS044075	Hobbs, E. (19??) Acute Toxicological Properties and Industrial Handling Hazards of Dow Corning® Fungicidal Additive. (Unpublished study received ? under an unknown admin. no.; prepared by Dow Corning Corp.)
GS044076	Hobbs, E. (19??) Acute Toxicological Properties and Industrial Hazards of Experimental Dow Corning® Fungicidal Additive, an Anti-Microbial Agent. (Unpublished study received ? under an unknown admin. no.; prepared by Dow Corning Corp.)
GS044077	Hobbs, E. (19??) Acute Toxicological Studies with Regard to the FHSA on a Potential Consumer Sealant, Dow Corning® Bathtub Caulk Containing Dow Corning® Fungicidal Additive. (Unpublished study received ? under an unknown admin. no.; prepared by Dow Corning Corp.)
GS044078	Hobbs, E. (19??) Acute Toxicological Studies with Regard to the FHSA on Experimental Building Sealant with Arsenic Fungicide. (Unpublished study received ? under an unknown admin. no.; prepared by Dow Corning Corp.)
00013591	International Paint Company (1957?) Report on the Comparative Toxicology of Phenarsazine oxide and Phenoxarsine oxide with Additional Data for the Inhalation Toxicity of DM. (Unpublished study received Sep 8, 1970 under 2693-21; CDL:105338-A)
GS044030	Kirkpatrick, D. (1977a) Laboratory report on Silicone Sealant, sample no. D805-3082. (Unpublished report received ? under an unkown admin. No.; prepared by the Consumer Protection Safety Commission; submitted by ?)

MRID	CITATION
GS044031	Kirkpatrick, D. (1977b) Laboratory report on Silicone Sealant, sample no. D805-3083. (Unpublished report received ? under an unkown admin. No.; prepared by the Consumer Protection Safety Commission; submitted by ?)
GS044033	Kohn, F.E.; Kay, D.L.; Stahoviak, E.F. (1968) Skin Irritation Study on Treated Fabric (Durotex 7603). (Unpublished study received ? under an unknown admin. No.; submitted by ?)
GS044079	Kohn, F.E.; Kay, D.L.: Stahoviak, E.F. (1968) Skin Irritation Study on Treated Fabric (Durotex 7599). (Unpublished study received ? under an unknown admin. No.; prepared by Lifestream Laboratories; submitted by Ventron Corp., Beverly, Mass.)
00024953	Kohn, F.E.; Kay, D.L.; Vega, S.M.; (1968) Acute Toxicity Studies on Durotex #7599. Summary of studies 025525-E through 025525-H. (Unpublished study received Mar 6, 1968 under 2829-89; prepared by Lifestream Laboratories, Inc.; submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:025525-G)
00024956	Kohn, F.E.; Kay, D.L.; Vega, S.M.; (1968) Eye Irritation Study--Albino Rabbits. (Unpublished study received Mar 6, 1968 under 2829-89; prepared by Lifestream Laboratories, Inc.; submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:025525-G)
GS044034	Kugler, D.J. (1974) Arsenic Survey at Ventron Corp.
GS044067	Lee, T. and Regel, L. (1974) Fish Toxicity. Testing Report of WARF Institute, No. 3121308.
GS044035	Leong, B.H.J. (1969) Result of a Respiratory Function Study and a Limited Histological Examination of Rats Exposed to OBPA. (Unpublished study received ? under an unknown admin. No.; prepared by Biochemical Research Laboratory, Dow Chemical Co., submitted by ?)
GS044039	Litton Bionetics, Incorporated (1978b) Acute Dermal Toxicity Study in Rats- 10-10'-oxybisphenoxarsine Final Report. Project No. 20936. (Unpublished study received ? under an unknown admin. No., submitted by Ventron Corp., Beverley, MA)
GS044041	Major Appliance Lab (1975) Physical Sciences Lab Report No. Ca-75-130 of Apr 1, 1971 to Howard Lester (Lester, Schwab, Katz, and Dwyer) on Darnell Case.

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MRID	CITATION
GS044042	McCollister, S.B.; Sparschu, G.L.; Spencer, H.C. (1969) Results of 92-Day Dietary Feeding Studies on OBPA in Rats. (Unpublished study received ? under an unknown admin. No.; prepared by Biochemical Research Laboratory, Dow Chemical Co., submitted by ?)
00024941	Olson, K.J. (1959) Acute Oral Toxicity. (Unpublished study received Nov 2, 1964 under unknown admin. No.; prepared by Biochemical Research Laboratory, submitted by ?; CDL:121914-H)
00024938	Olson, K.J. (1959) Eye Contact Test. (Unpublished study received Nov 2, 1964 under unknown admin. No.; prepared by Biochemical Research Laboratory, submitted by ?; CDL:121914-D)
00024937	Olson, K.J. (1959) Skin Contact--Irritation. (Unpublished study received Nov 2, 1964 under unknown admin. No.; prepared by Biochemical Research Laboratory, submitted by ?; CDL:121914-C)
00026092	Olson, K.J.; Nunemaker, R.B.; Shrader, S.A.; et al. (1959) Skin Contact Absorption. (Unpublished study received Nov 2, 1964 under unknown admin. No.; prepared by Biochemical Research Laboratory in cooperation with Dow Chemical Co., submitted by ?; CDL:121914-F)
00024940	Oxen, F. (1959) Summary of Pathology on Male & Female Rats Fed 10, 10'-Oxybisphenoxarsine in the Diet for 30 days. (Unpublished study received Sep 2, 1965 under unknown admin . No.; submitted by ?; CDL:121914-G)
GS044048	Porter, W.K. (1973) U.S. Consumer Product Safety Commission's Analyst Worksheet on G.E. Silicone sealer white, Nov 11.
00023386	Powers, M.B. (1968) Acute Oral Toxicity--Rats: Final Report: Project No. 349-163. (Unpublished study received Feb 22, 1974 under 2829-105; prepared by Hazelton Laboratories, Inc.; submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:025537-F)
GS044068	Skinner and Sherman, Inc. (1968) Technical Report: Vapor Presure. Ventron Chemicals Division. Case No. 9837.
GS044055	United States Department of Health, Education, and Welfare (1962) Public Health Service Drinking Water Standards, 1962. Public Health Service Publication No. 956, Washington, DC, U.S. Government Printing Office.

MRID	CITATION
GS044070	United States Environmental Protection Agency (EPA) (1979) Removal of OBPA from Rebuttable Presumption Against Registration. Decision Document prepared by Herman Gibb, Project Manager.
00013622	Ventron Corporation (1975) Analytical Laboratory Report: Stability Data for OBPA and Solid Biocides Containing OBPA. (Unpublished study received Mar 22, 1976 under 2829-115; CDL:226170-A)
00013625	Ventron Corporation (1976) Process: Description of Manufacturing Process. (Unpublished study received Mar 22, 1976 under 2829-115; CDL:226170-D)
GS044056	Ventron Corporation (1978) Extraction of 10,10'-Oxybisphenoxarsine from Plasticized Vinyl Films.
GS044069	Ventron Corporation (1981) pH of Technical OBPA.
05016437	Wade, R.C., inventor; Ventron Corp., assignee (1972) Method for preparing 10-chlorophenoxarsine. U.S. patent 3,701,794. Oct 31. 2 p. Int. Cl. C 07d 105/06; U.S. Cl. 260-440.
00013631	WARF Institute, Incorporated (1971) Report: WARF No. 1030508. (Unpublished study received Feb 5, 1976 under 2829-115; submitted by Ventron Corp., Beverly, Mass.; CDL:226171-H)
00013611	WARF Institute, Incorporated (1973) Report: WARF No. 3031960. (Unpublished study received May 31, 1973 under 2829-96; submitted by Ventron Corp., Beverly, Mass.; CDL:006984-D)
00013610	WARF Institute, Incorporated (1973) Report: WARF No. 3031960. (Unpublished study received May 31, 1973 under 2829-96; submitted by Ventron Corp., Beverly, Mass.; CDL:006984-C)
00023384	WARF Institute, Incorporated (1974) Report: WARF No. 3121308. (Unpublished study received Feb 22, 1974 under 2829-105; submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:025537-D)
00023377	WARF Institute, Incorporated (1974) Report: WARF No. 4041382. (Unpublished study received Jun 14, 1974 under 2829-93; submitted by Thiokol Corp., Ventron Div., Danvers, Mass.; CDL:221989-A)
00013632	WARF Institute, Incorporated (1975) Report: WARF No. 5062466. (Unpublished study received Feb 5, 1976 under 2829-115; submitted by Ventron Corp., Beverly, Mass.; CDL:226171-I)

MRID	CITATION
00013636	WARF Institute, Incorporated (1975) Report: WARF No. 5062467. (Unpublished study received Feb 5, 1976 under 2829-115; submitted by Ventron Corp., Beverly, Mass.; CDL:226171-N)
00013629	WARF Institute, Incorporated (1975) Report: WARF No. 5103842. (Unpublished study received Feb 5, 1976 under 2829-115; submitted by Ventron Corp., Beverly, Mass.; CDL:226171-F)
00013630	WARF Institute, Incorporated (1976) Report: WARF No. 5121270. (Unpublished study received Feb 5, 1976 under 2829-115; submitted by Ventron Corp., Beverly, Mass.; CDL:226171-G)
GS044057	WARF Institute, Incorporated (1976a) Report: WARF No. 6013735, Acute Oral LD_{50} and Acute Dermal LD_{50}/Durotex 7603.
00013653	WARF Institute, Incorporated (1977) Report: WARF Institute No. 7033536. (Unpublished study received Jun 12, 1977 under 2829-96; submitted by Ventron Corp., Beverly, Mass.; CDL: 230703-C)
GS044060	WARF Institute, Incorporated (1977b) Report: WARF No. 6112742, Acute Oral LD_{50}, Vinyzene SB-1.
GS044061	WARF Institute, Incorporated (1977c) Report: WARF No. 6112742, Skin Irritation, Vinyzene SB-1.
00013661	WARF Institute, Incorporated (1978) Report: WARF Institute No. 7116139. (Unpublished study received Jan 27, 1978 under 2829-117; submitted by Ventron Corp., Beverly, Mass.; CDL: 232999-B)
00013662	WARF Institute, Incorporated (1978) Report: WARF Institute No. 7117217. (Unpublished study received Jan 27, 1978 under 2829-117; submitted by Ventron Corp., Beverly, Mass.; CDL: 232999-C)
00013663	WARF Institute, Incorporated (1978) Report: WARF Institute No. 7117218. (Unpublished study received Jan 27, 1978 under 2829-117; submitted by Ventron Corp., Beverly, Mass.; CDL: 232999-D)
00013660	WARF Institute, Incorporated (1978) Report: WARF Institute No. 7117219. (Unpublished study received Jan 27, 1978 under 2829-117; submitted by Ventron Corp., Beverly, Mass.; CDL: 232999-A)

MRID	CITATION
GS044062	Weingast, J. (1976) Arsenic Survey at Ventron Corp.
GS044066	Yeager, C.C. (1976) Physical Properties of OBPA. (Unpublished study submitted by Ventron Corporation)
00013601	3M Company (1970) Summary: Toxicological Data. Summary of studies 230572-C through 230572-F. (Unpublished study received Nov 15, 1971 under 10350-3; CDL:230572-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD ALPHABETICAL BIBLIOGRAPHY
Section 2: Citations Considered Not Part of the Data Base Supporting Registration Under the Standard

MIRD	CITATION
05018655	Akagane, K.; Allan, G.G. (1973) Choki boosei no kenkyu. (Dai-5-po). Tashu no dokubutsu yorinaru A/F kobunshishu no kassei dokubutsu-kan no sogo sayo. [Studies on long term protection. V. Mutual interactions of active toxicants in antifouling polymers consisting of multicomponent toxicants.] Shikizai Kyokaishi. [Journal of the Japan Society of Color Materials.] 46(8):437-442.
05018510	Akagane, K.; Matsuura, K. (1972) [Long-term protection. I. Effects of toxic polymers on long-term protection.] Shikizai Kyokaishi. [Journal of the Japan Society of Color Materials.] 45(2):69-74.
05015858	Alarie, Y.; Lin, C.K.; Geary, D.L. (1974) Sensory irritation evoked by plastic decomposition products. American Industrial Hygiene Association Journal 35(10):654-661.
GS044080	Aldous, K.M. (1977) Analysis of Silicone Cauking Compounds for Arsenic Content. (Unpublished study prepared by the N.Y. State Department of Health)
GS044001	Anspach, P.S. (1977) Acute Toxicity and Irritation Studies of 99.9% 10,10'-Oxybisphenoxarsine. (Unpublished study prepared by International Bio-Research, Inc., Cincinnati, OH, Feb. 1)
GS044003	Aldous, K.M. (1977) Analysis of Silicone Cauking Compounds for Arsenic Content. (Unpublished study prepared by the N.Y. State Department of Health)
GS044005	Bailey, E.M.; Zimgaro, R.A. (1978) Toxicologic and Mutagenic Properties of OBPA and its Formulations.
GS044006	Biesemeier, J.A. (1975) Vinyzene SB-1: Acute Oral LD_{50}; Acute Dermal LD_{50}. Testing report of WARF Institute, Inc., Madison, WI, Nov. 19.
GS044008	Biochemical Research Laboratory, Dow Chemical Company (1960) Results of a 35-Day Dietary Feeding Study of OBPA to Rats.
05017159	Brown, F.L.; Gooch, R.M. (1968) 10,10'-Oxybisphenoxarsine—a candidate wood preservative. Wood Science 1(1):41-46

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GS044010	Cadmus, E.L. (19??) The Biological Stability of Polymers. (Unpublished study prepared by Ventram Corporation)
00013671	Cadmus, E.L. (1972) Laboratory Report: Extractability of Vinyzene BP-10: Test No. 12269. (Unpublished study received Jan 23, 1973 under 2829-93; submitted by Ventron Corp., Beverly, Mass.; CDL: 240463-A)
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00013618	Cadmus, E.L. (1973) Laboratory Report: Extractability of Vinyzene BP-5: Test No: 12424. (Unpublished study received Apr 5, 1973 under 2829-82; submitted by Ventron Corp., Beverly, Mass.; CDL: 101719-A)
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